Exhibit C

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	Master File No. 2:12-MD-MDL 2327
THIS DOCUMENT RELATES TO THE CASES LISTED BELOW	:	JOSEPH R. GOODWIN US DISTRICT JUDGE

Mullins, et al. v. Ethicon, Inc., et al.
2:12-cv-02952
Sprout, et al. v. Ethicon, Inc., et al.
2:12-cv-07924
Iquinto v. Ethicon, Inc., et al.
2:12-cv-09765
Daniel, et al. v. Ethicon, Inc., et al.
2:13-cv-02565
Dillon, et al. v. Ethicon, Inc., et al.
2:13-cv-02919
Webb, et al. v. Ethicon, Inc., et al.
2:13-cv-04517
Martinez v. Ethicon, Inc., et al.
2:13-cv-04730
McIntyre, et al. v. Ethicon, Inc., et al.
2:13-cv-07283
Oxley v. Ethicon, Inc., et al.
2:13-cv-10150
Atkins, et al. v. Ethicon, Inc., et al.
2:13-cv-11022
Garcia v. Ethicon, Inc., et al.
2:13-cv-14355

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- - -

October 2, 2015
VIDEOTAPED DEPOSITION MARC TOGLIA, M.D.

GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph| 917.591.5672 fax
deps@golkow.com

CAPTION CONTINUED:

Lowe v. Ethicon, Inc., et al.
2:13-cv-14718
Dameron, et al. v. Ethicon, Inc., et al.
2:13-cv-14799
Vanbuskirk, et al. v. Ethicon, Inc., et al.
2:13-cv-16183
Mullens, et al. v. Ethicon, Inc., et al.
2:13-cv-16564
Shears, et al. v. Ethicon, Inc., et al.
2:13-cv-17012
Javins, et al. v. Ethicon, Inc., et al.
2:13-cv-18479
Barr, et al. v. Ethicon, Inc., et al.
2:13-cv-22606
Lambert v. Ethicon, Inc., et al.
2:13-cv-24393
Cook v. Ethicon, Inc., et al.
2:13-cv-29260
Stevens v. Ethicon, Inc., et al.
2:13-cv-29918
Harmon v. Ethicon, Inc., et al.
2:13-cv-31818
Snodgrass v. Ethicon, Inc., et al.
2:13-cv-31881
Miller v. Ethicon, Inc., et al.
2:13-cv-32627
Matney, et al. v. Ethicon, Inc., et al.
2:14-cv-09195
Jones, et al. v. Ethicon, Inc., et al.
2:14-cv-09517
Humbert v. Ethicon, Inc., et al.
2:14-cv-10640
Gillum, et al. v. Ethicon, Inc., et al.
2:14-cv-12756
Whisner, et al. v. Ethicon, Inc., et al.
2:14-cv-13023
Tomblin v. Ethicon, Inc., et al.
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Schepleng v. Ethicon, Inc., et al.
2:14-cv-16061
Tyler, et al. v. Ethicon, Inc., et al.
2:14-cv-19110
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Kelly, et al. v. Ethicon, Inc., et al.
2:14-cv-22079
Lundell v. Ethicon, Inc., et al.
2:14-cv-24911
Cheshire, et al. v. Ethicon, Inc., et al.
2:14-cv-24999
Burgoyne, et al. v. Ethicon, Inc., et al.
2:14-cv-28620
Bennett, et al. v. Ethicon, Inc., et al.
2:14-cv-29624

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OCTOBER 2, 2015

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Videotape deposition of MARC TOGLIA, M.D., taken pursuant to notice, was held at the law offices of Drinker Biddle and Reath, LLP, One Logan Square, 18th and Cherry Streets, Suite 2000, Philadelphia, Pennsylvania 19103, commencing at 1:26 p.m., on the above date, before Amanda Dee Maslynsky-Miller, a Certified Realtime Reporter and Notary Public in and for the State of Pennsylvania.

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Representing the Defendant

ALSO PRESENT: Gregory Fields, Videographer

- - -

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(It is hereby stipulated and agreed by and among counsel that sealing, filing and certification are waived; and that all objections, except as to the form of the question, will be reserved until the time of trial.)

- - -

THE VIDEOGRAPHER: We are now on the record. My name is Gregory Fields. I'm a videographer for Golkow Technologies. Today's date is October 2nd, 2015, and the time is 1:26 p.m. This video deposition is being held in Philadelphia, Pennsylvania, in the matter of In Re: Ethicon, U.S. District Court, Southern District of West Virginia. The deponent is Marc Toglia. Counsel will be noted on the stenographic record. The court reporter is Amanda Miller

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and will now swear in the witness.

- - -

MARC TOGLIA, M.D., after having been duly sworn, was examined and testified as follows:

- - -

EXAMINATION

- - -

BY MS. THOMPSON:

Q. Dr. Toglia, I'm Margaret Thompson, I represent the plaintiffs in their case against Ethicon.

And you understood that -- you understand that that's why you're here today?

A. Yes, I do.

Q. Could you please state your name for the record?

A. Yes. Marc Richard Toglia.

Q. And what is your occupation, Dr. Toglia?

A. I'm a physician.

Q. Do you have a specialty?

A. Yes. I'm board certified in

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female pelvic medicine and reconstructive surgery.

Q. Are you also board certified in OB/GYN?

A. That is correct. I'm double board certified.

Q. What is your office address currently?

A. It's 1098 West Baltimore Pike, Media, Pennsylvania, Healthcare Center 3, Suite 3404.

Q. And who is your employer?

A. I'm employed by Main Line Healthcare.

Q. Do you have an academic appointment as well?

A. I have several. I'm an associate professor of obstetrics and gynecology at what we formerly called Thomas Jefferson School of Medicine, is now the Sidney Kimmel School of Medicine.

And I'm also an associate professor, clinical associate professor at the Lankenau Institute of Medical

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Research.

Q. So am I understanding correctly that you have a private practice as well as your academic appointment?

A. Yes.

Q. So you're paid by the academic institutions and then you also have -- receive income from your private practice; is that correct?

A. There's no financial compensation for the academic appointments.

Q. For either --

A. For the --

Q. -- one of the academic appointments?

Okay. So your income, then, is derived strictly from your private practice of urogynecology?

A. That is correct.

Q. And would you consider that a specialty practice?

A. It's a subspecialty

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practice.

Q. A subspecialty practice.

So you are a referral practice, so to speak?

A. Yes. I exclusively take care of women that have urinary incontinence and pelvic floor disorders.

Q. And are those patients typically referred to you by other physicians?

A. My patients may come from sisters, mothers, former patients, other physicians. The bulk of my practice probably comes from other physicians.

Q. And do you do, as part of that subspecialty practice, general GYN as well or restrict it completely to urogynecology?

A. I don't consider my practice general gynecology. I mean, occasionally a gynecologist may send me a patient for an opinion that might have a general gynecology, but that's not what I hold myself out as.

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Q. So, typically, you would not be doing annual checkups, Pap smears, mammograms, birth control, that sort of thing that a general gynecologist might do?

MR. SNELL: Hold on. Objection. Compound. Overbroad. Go ahead.

THE WITNESS: No.

BY MS. THOMPSON:

Q. And when you're treating a patient for a urogynecological condition, we'll get to what those are a little bit later, and that condition is resolved, do you then send that patient back to their general gynecologist or primary care physician?

A. Yes.

Q. And that would be because, one of the reasons, at least, is that physicians don't want to send their patients to a subspecialty and then lose their patients to their care; is that right?

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A. I don't know that I would agree with that statement. Let me clarify that. I take care of chronic disease.

So it's not unusual for us to maintain a lifetime relationship with these patients. But if I understand you correctly, if I were to take care of a specific pelvic floor disorder and that person was to need, say, a mammogram, a Pap smear or some other kind of primary care service, we are not the ones primarily responsible for that, and they would go back to their referring doctor or the doctor of their choosing.

Q. Understood. And what if the patient's pelvic floor disorder is cured, same thing?

A. Yes.

Q. What hospitals do you currently have privileges at?

A. Currently, I'm privileged at all four of Main Line Healthcare hospitals. The Main Line Healthcare

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hospital system is located in suburban Philadelphia; it consists of Lankenau Medical Center, Bryn Mawr Hospital, Paoli Hospital and Riddle Hospital.

Q. And do you do surgeries at all four of those facilities as well?

A. No.

Q. Which ones do you perform surgeries at?

A. I will operate at Riddle Hospital, Paoli Hospital and Lankenau Medical Center. My schedule does not allow me to operate at, say, Bryn Mawr Hospital. Although I have, from time to time, gone through; but I don't consider that to be a hospital that I would use for surgical procedures.

Q. Do you have privileges or do surgery at any type of surgical center, freestanding surgical center?

A. I do not.

Q. So minor surgeries or those that would be output surgeries are done in the hospital as well?

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A. I think, technically, the outpatient surgical surgeries are on hospital property, but I think that they are designated as -- you know, there's ambulatory surgery.

Q. Are they on a different floor --

A. No.

Q. -- from the main operating room?

A. It's all -- it's the same. I mean, patients are classified by their status not by physical location.

Q. Okay. Are you married, Dr. Toglia?

A. I am.

Q. Children?

A. Yes.

Q. How many?

A. I have two children.

Q. What are their ages?

MR. SNELL: Not relevant. Don't answer that question.

MS. THOMPSON: You're

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instructing him not to answer?
MR. SNELL: Yes. That's private. About his children? He came here to give opinions on the defect and the question that, that the judge posed about TVT, not to tell you about his children.
MS. THOMPSON: I'm just getting to know him.
MR. SNELL: No, that's not appropriate. I don't ask your experts about who their children are and their ages and stuff. That is totally inappropriate.
BY MS. THOMPSON:
Q. You can go ahead and answer.
MS. THOMPSON: Unless you're instructing him not to answer?
MR. SNELL: Yes, I'm instructing him not to answer. I think that violates his privacy, is totally outside the scope, is not relevant.
MS. THOMPSON: Okay. Object

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to form is sufficient.
THE WITNESS: Thank you. I appreciate that. And I agree.
BY MS. THOMPSON:
Q. Have you given previous depositions?
A. Yes.
Q. How many?
A. I honestly couldn't tell you off the top of my head. Probably no more than a dozen. I don't think I've given a deposition in over ten years, to the best of my -- my knowledge.
Q. So somewhere in the range of five to twelve, would you ballpark it?
A. Yes.
Q. And what types of cases were those depositions given in?
A. The vast majority of them, if not all of them, were within the realm of female pelvic floor disorders, areas of my expertise, which oftentimes extends into the obstetrical world.
Q. So am I correct those would

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be medical malpractice cases?
A. Most of them are medical malpractice cases.
My reason for pausing, I think one actually involved a piercing or tattoo parlor that was involved. And I don't think that's medical malpractice, but there were medical claims.
Q. And did you testify for the defense or the plaintiffs or a mix in those cases?
A. I've done a mix.
Q. Did any of those cases that you have given depositions in relate to mesh products?
A. To the best of my knowledge, no.
Q. Dr. Toglia, did you --
- - -
(Whereupon, Exhibit Toglia-1, Notice of Videotaped Deposition Pursuant to Rule 30 and Document Requests Pursuant to Rule 34 of Marc Toglia, M.D., was

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marked for identification.)
- - -
MS. THOMPSON: We've marked as Exhibit-1 the notice for your deposition today.
MR. SNELL: Thank you.
BY MS. THOMPSON:
Q. Have you had a chance to --
MR. SNELL: Let me -- I just want to give him the original, that way the ones don't get mixed up.
MS. THOMPSON: Sure. Thank you.
BY MS. THOMPSON:
Q. Have you had a chance to see this document prior to just now?
A. I have.
Q. When did you first see this?
A. I was given this document, probably, near the end of last week, to the best of my knowledge.
Q. And did you see Schedule A, which is attached to the notice of

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deposition?
A. Yes.
Q. And it asked you to bring, oh, a whole bunch of documents. And I'm not going to go through these individually.
But can you just tell me what you brought with you today?
A. Yes. To the best of my knowledge, I have brought, as you put it, as a whole bunch of documents, as they relate to Schedule A.
Q. And those are contained in the -- some boxes that you brought to the conference room?
A. Yes. Some are electronic, the majority of them are copied on paper.
Q. And I think Mr. Snell provided me a flash drive with everything that's in the boxes, correct?
MR. SNELL: As far as I know. Although, he's brought thumb drives, too.
MS. THOMPSON: Okay.

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MR. SNELL: So, I mean -- and also, I mean, you may want to ask him, but he's done his own research. So he may have stuff that I don't even have.
MS. THOMPSON: I think I should do that.
BY MS. THOMPSON:
Q. Dr. Toglia, could you just go through what you brought here and describe what you have? Not document by document, but generally speaking.
A. Generally speaking, I have brought the relevant clinical studies and other published research, as well as the legal documents, including the expert reports and depositions.
Q. Did you bring anything with you that is not included on your -- the reliance list that's attached to your report?
A. Obviously, I can't claim to have an independent knowledge of every specific element on that list, but to the

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best of my knowledge, I have done my best to comply and everything is -- is as it is listed.
MR. SNELL: I will make one note, just for a clean record, too, as he did say, since the time he published his report and his reliance materials list, there have been depositions of your experts. He, obviously, has those and I think he might have even said that.
But when she asks you a question you are allowed to take them and look at them and tell her what you reviewed.
THE WITNESS: Understood.
MS. THOMPSON: And we'll maybe take a brief look at it at the break.
MR. SNELL: That's fine. He brought it here, it's up to you. You can look at it, copy it, do whatever you want.

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MS. THOMPSON: I appreciate that.
BY MS. THOMPSON:
Q. Did you bring any billing records with you today?
MR. SNELL: I have those. I have them somewhere.
Let's go off the record for a second.
VIDEO TECHNICIAN: We are off the record. The time is 1:38 p.m.
- - -
(Whereupon, a discussion off the record occurred.)
- - -
VIDEO TECHNICIAN: We are back on the video record.
BY MS. THOMPSON:
Q. Dr. Toglia, I think you brought your report that you prepared in this case --
A. Yes.
Q. -- is that correct?

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- - -
(Whereupon, Exhibit Toglia-2, Expert Report of Marc R. Toglia, M.D., was marked for identification.)
- - -
BY MS. THOMPSON:
Q. And we have marked that as Exhibit Number 2.
I believe you have your own copy as well?
A. I do.
Q. Do you have any notes on your copy that you brought with you?
A. I mean, I've got some underlines in pencil. I may have made a spelling correction. I don't have any prose of any kind in there.
Q. There's a curriculum vitae attached to that report --
A. Yes.
Q. -- as you recall.
Is that a current C.V.?
A. It is.

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Q. Are there any additions that you would make to that, sitting here today --
A. No.
Q. -- that you can think of?
MS. THOMPSON: So Exhibit-2 will be the report and the -- with the C.V.
- - -
(Whereupon, Exhibit Toglia-3, Invoices, was marked for identification.)
- - -
BY MS. THOMPSON:
Q. And it looks like you also brought, today, two bills or invoices for your work in this case, and we've marked that as Exhibit Number 3.
A. Thank you.
Q. Do those look familiar?
A. Yes.
Q. And the last date on the invoice is September 24th.
Can you approximate how many

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hours you have worked on this case since September 24th? That would be in the last week or so.
A. Would it be sufficient if I told you that I've probably done -- used a total of about 50 hours in total?
Q. So 50 hours total on this case to date?
A. 50 hours --
Q. Approximately?
A. Approximately 50 hours of work on this case.
Q. How many hours did you spend preparing your report, approximately?
A. Approximately 23 years and 50 hours.
And the reason why I say that, counselor, is that most of the material that I have reviewed, I have reviewed over the span of my career. And that would include, perhaps, reviewing it prior to being published, watching it be presented at meetings, having read it over and over for my own personal, you

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know, knowledge and interest.
And, certainly, many of these articles relate to the subspecialty board certification.
Q. But you haven't billed Ethicon for 23 years, correct?
A. I've told you that I've billed them for 50 hours, counselor, right. In formulating my opinion.
Q. I'm just trying to break -- break it down a little bit --
A. Sure.
Q. -- and try to understand how much of that 50 hours was actually preparing your report.
And if you can't -- if you're not -- unable to do that, that's fine.
A. In preparing the report, it probably is, both of these, 10 hours plus 33 hours, 43 hours; and the difference is probably split between preparing for the deposition and additional work finalizing the report.

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Q. So that would include review of literature, for instance?
A. Correct.
Q. When were you first contacted to serve as an expert in this case?
A. If memory serves me right, it was some time in August.
Q. And do you have any correspondence regarding that initial contact?
A. I do not.
Q. Was it a phone call?
A. Correct.
Q. From Mr. Snell or another attorney?
A. From Mr. Snell.
Q. And what did Mr. Snell ask you to do?
A. Mr. Snell apprised me to the existence of the case and that he needed to retain an expert to specifically comment on the claims as they relate to the safety, the design of the TVT

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product.
Q. Did he provide you with materials to review?
A. Mr. Snell provided me with, I believe, the original complaint and, of course, my access to the internal documents from the company and from the plaintiffs' experts and the exhibits.
Q. Did he also provide you with literature?
A. Yes.
Q. And so on your reliance list that's attached to your report, does that include the literature that Mr. Snell provided you?
A. To be completely honest with you, there was very little on that list that I was not already familiar with.
Q. So you were familiar with the majority of the articles on the list.
But the list was provided by counsel; is that correct?
MR. SNELL: Correct, yes.
THE WITNESS: Yes.

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MR. SNELL: I will say that I -- I provided this list.
MS. THOMPSON: Fair enough.
BY MS. THOMPSON:
Q. And these were the articles that Mr. Snell provided you with as well?
A. Yes.
MR. SNELL: I will make one note for the record. He sent articles and things to me that I told paralegals to put on this list, okay?
MS. THOMPSON: Fair enough.
MR. SNELL: So I tried to capture whatever he went out and found, just so you would have it.
BY MS. THOMPSON:
Q. So the list would include articles that Mr. Snell provided you, articles that you thought were relevant that you sent back to him, and those were just --
A. Right. And to be clear, there was a large degree of duplication

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between things that I had already had in my possession and things that were on his list.
Q. And I actually noticed that there were some duplications on the list itself, because of minor variations in the citation or whatever.
And, I guess, that might have been the case on some of those, correct?
A. Counselor, I'm sorry, I'm not -- I'm not familiar with what, specifically, you're referring to or what you're --
Q. Okay. Are all the opinions that you intend to provide at trial contained in this report?
A. Yes. With the exception of anything that I might discover, you know, between now and then that might be of relevance.
Q. Okay. And you mentioned depositions that you reviewed. And some of those are listed on the reliance list,

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if you look on the last page.
Are there any that come to mind that you've reviewed in addition to these?
A. I'm not sure that I have what you're referring to as a reliance page.
Q. Attached to your report.
A. Oh, I'm sorry.
Yes, I would say the ones that come to mind would be the deposition -- the recent depositions of the plaintiffs' experts, which would include Dr. Blaivas, Dr. Rosenzweig and Dr. Elliott.
Q. So the depositions of Drs. Blaivas, Rosenzweig and Elliott are in addition to the reports listed here?
A. Correct.
MR. SNELL: I'll make a note, for the record, that he may have opinions regarding those expert depositions.
BY MS. THOMPSON:

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Q. Do you have any opinions related to the expert depositions that you reviewed that you can relate to me at this time?
A. I do.
Q. Why don't you go ahead -- that are different from what you have in your report?
A. I don't know that I would say different. They would be, maybe, perhaps, in addition. That I might have opinions in addition to what I may have expressed in the report, if that makes sense to you.
Q. Sure. Why don't you go ahead and, to the best of your ability, give me those additional opinions now?
A. Where would you like me to start?
Q. Wherever you want to start.
MR. SNELL: You can -- do you want the depositions?
THE WITNESS: Would it be helpful for you, counselor, if,

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perhaps, I explain to you my methodology, as far as what -- what I did in terms of formulating the opinion and what I found, what I -- what I was told was sort of my charge, so to speak?
BY MS. THOMPSON:
Q. Sure.
A. I think that will just make what I'm about to say more -- sort of more relevant.
So it was my understanding that I was to formulate an opinion whether or not the design of the TVT was reasonably safe for its intended use for the treatment of stress incontinence in women versus whether or not it was defective in its design.
In formulating my opinion, I looked at the high-quality studies. By that I mean those that we would consider to be Level 1 evidence, things such as randomized control trials, systematic reviews, the prospective longitudinal

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registry trials. All of these would constitute what we would consider to be Level 1 scientific evidence.
From there, I reviewed the published position statements from the relevant specialty societies. And those would be sort of the high-quality data that I used to formulate my opinion.
There were additional pieces of works, such as those exhibits -- I don't always know the legal term for these things -- that were provided by your experts, by the plaintiffs' experts that, of course, I would have looked at and considered, because, obviously, they were relevant in that regard.
I will tell you, just to be clear, that, in general, things like bench research, in vitro studies, case series, we consider those to be Level 5 -- expert opinion, Level 5 studies. And those, typically, are not very relevant or scientifically meaningful, especially when Level 1 evidence exists.

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And so those things, because of their severe limitations, you can never derive clinical inference or medical conclusions, because the evidence is so weak.

So while I am familiar and have reviewed those studies and documentations, typically, they don't factor into the formulation of an opinion.

In that regard, I would say, as a general statement, I was struck by the fact that all three of the expert reports that I reviewed, and I'm specifically referring to those by Dr. Rosenzweig, Blaivas and Elliott, that they were significantly devoid of similar high-quality Level 1 evidence studies and seemed to spend the majority of their time looking at far less clinically relevant Level 5 studies, such as animal studies, bench research, in vitro studies, unpublished observations, as well as personal experience and expert

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opinion.

So as a general statement, my additional opinion is that, you know, the majority of what I've read from these individuals is not of very high scientific quality.

And I think that they have, if I can be completely honest, misrepresented data from levels of evidence that do not allow you to make clinical inference or draw conclusions specifically as it would relate to the design and safety of the TVT device and specifically to its intended use for the treatment of female stress incontinence.

Q. Let's go ahead and get to the additional opinions that you have, with that background.

A. Yes.

Q. What are those additional opinions?

A. I think I've given you what -- what those opinions are. I mean, if you have specific questions, I'm more

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than happy to discuss those with you.

Q. All right. So it sounds like the additional opinion that you're giving are that the plaintiff experts' reports are devoid of high-quality studies?

MR. SNELL: Objection. He told you a lot more than that.

THE WITNESS: Yes. I don't think --

BY MS. THOMPSON:

Q. I think that's --

A. -- I can simplify it into a single sentence.

Q. Now, you'll agree with me that a position statement is not a scientific study, correct?

A. A scientific -- I would not agree with that statement. And let me clarify.

A position statement is a summary statement typically based upon a systematic review or independent analysis of Level 1 data.

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Q. But it's not a scientific piece of literature? It's not peer reviewed, is it?

MR. SNELL: Objection. Asked and answered.

THE WITNESS: I disagree. They -- they are peer reviewed. All position statements are formulated and then reviewed prior to publication. In fact, the majority of them, for example, you'll see, are published in peer-reviewed journals. You cannot be published in a peer-reviewed journal unless you are peer reviewed.

BY MS. THOMPSON:

Q. Okay. Well, let's just consider the AUGS position statement on midurethral slings.

You're familiar with that document, correct?

A. Yes. I have that document here in my possession.

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Q. Do you know why that was prepared?
A. Do I know why? Can you -- I'm not sure if I understand what you're -- what you're meaning.
Q. What was the purpose for the preparation of that position statement by AUGS?
A. The AUGS position statement was -- was created to, as I stated, to provide a summary statement based upon high-quality scientific evidence in light of -- I'm sorry for putting this, unfounded claims regarding the design defects and similar type statements.
Q. So if I told you that the purpose, the reason that the AUGS position statement was written was to use in courtrooms, in litigation, would you have any reason to doubt that?
A. Yes.
MR. SNELL: Hold on. Let me -- let me -- you have to give me a chance to object.

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THE WITNESS: Sorry.
MR. SNELL: Objection. Lacks foundation.
Go ahead.
THE WITNESS: That absolutely was not the reason.
BY MS. THOMPSON:
Q. And you're confident of that?
A. I am confident of that, yes.
Q. Okay. And are you familiar with the authors of that position statement?
A. Yes.
Q. Are you familiar with the authors' industry ties?
A. I can't tell you that I know in any great detail what their ties are.
Q. If I told you that they all have conflicts of interest regarding their financial relationship with industry, would you have any reason to doubt that?
A. Yes.

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MR. SNELL: Hold on. Let me -- you have to give me -- these are totally without -- objection. Lacks foundation. Misstates evidence.
Go ahead.
THE WITNESS: I would not believe what you're saying. Or I don't believe what you're saying.
BY MS. THOMPSON:
Q. Is there anywhere in that two-page position statement that mentions complications or risks associated with midurethral slings?
A. May I refer to it?
MR. SNELL: Of course.
MS. THOMPSON: Sure.
MR. SNELL: You can always get it out.
That goes for any document she asks you about.
THE WITNESS: Of course, it has to be the one that's all the way at the back.

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MR. SNELL: Just so I'm clear on the record, which one are you talking about?
MS. THOMPSON: The AUGS position statement on midurethral slings.
MR. SNELL: There's a couple.
THE WITNESS: There's one. There's --
MS. THOMPSON: I'm only familiar with one position statement.
- - -
(Whereupon, a discussion off the record occurred.)
- - -
THE WITNESS: Counselor, thank you for waiting.
I have in front of me the AUGS/SUFU position statement on mesh midurethral slings. I would ask that you repeat the question to me, please.

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BY MS. THOMPSON:
Q. The question is, in this, actually, three-page position statement, is there any mention of complications or risks associated with midurethral slings?
A. I believe that the purpose of the position statement was to acknowledge the fact that the midurethral sling was recognized as the worldwide standard of care and that the procedure was felt to be safe and effective.
I don't believe that this was a document that was intended to address the question that you're asking me.
Q. So the answer is no?
MR. SNELL: Objection. Misstates.
MS. THOMPSON: Well, it's a yes-or-no question.
BY MS. THOMPSON:
Q. Is there any mention of complications or risks in this three-page document?

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MR. SNELL: He just told you it discussed the safety.
MS. THOMPSON: He said -- okay.
BY MS. THOMPSON:
Q. Let's -- show me where it discusses the safety.
A. Counselor, on Page 2, under Number 4, The FDA has clearly stated that polypropylene midurethral sling is safe and effective in the treatment of stress urinary incontinence.
In this document it is explicitly stated, That the FDA -- and I'll just paraphrase, The safety and effectiveness of multi-incision slings is well established in clinical trials.
Q. It still doesn't -- it says it's safe.
Does it discuss complications?
A. Counselor, the question that you asked me is whether or not it was safe. I answered the question.

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Q. I said -- there's a discussion of safety. That, to me, is not a discussion of safety.
MR. SNELL: Objection. That is not a question. Move to strike the attorney comment.
BY MS. THOMPSON:
Q. Are there any complications of midurethral slings discussed in this position paper?
A. Again, that was not the purpose of the paper. So I am not surprised that there would not be a specific discussion of that in that particular paper.
But, again, that was one of a series of papers that AUGS published on that.
Q. So your position is that the purpose of this position statement by AUGS and SUFU was to report on the clinical studies related to midurethral slings, but it was not necessary to comment on any complications or risks

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associated; is that your testimony?
MR. SNELL: Objection.
THE WITNESS: That's not what I --
MR. SNELL: Hold on. Objection. Misstates testimony.
MS. THOMPSON: I'm asking if that's his testimony. If it's not, he can tell me it's not.
THE WITNESS: It is not my testimony, counselor.
Again, to be clear, a position statement is exactly that, it's a statement on a position. And the position taken here was specifically and simply, midurethral slings are recognized as the worldwide standard of care for the treatment of stress urinary incontinence.
The statement is that the procedure is safe, effective and has improved the quality of life for millions of women.

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BY MS. THOMPSON:
Q. So, then, a position statement is an opinion, correct?
A. A position statement is an opinion.
Q. And I don't think we ever answered my question if there were any complications discussed, but I'd like for you to answer that yes or no.
Were -- are any complications discussed in the position statement?
MR. SNELL: Objection. Asked and answered.
MS. THOMPSON: He has not answered it.
THE WITNESS: That wasn't the purpose of the -- of the position statement.
BY MS. THOMPSON:
Q. I didn't ask about the purpose.
I asked you, are complications or risks discussed in this

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position statement?
A. They are not discussed in the position statement.
Q. Thank you.
Let's go back to the Schedule A on the notice of deposition. I want to ask you just about a handful of items to see if you brought them or had them in your possession.
Number 13, do you -- did you bring any Ethicon products in your possession?
A. I have no Ethicon products in my possession.
Q. The documents or communications relating to presentations or lectures given to you concerning pelvic mesh, pelvic organ prolapse or stress urinary incontinence, did you bring those items with you?
A. I'm sorry, I'm not -- I'm not --
Q. Number 16. Sorry.
A. Okay. I'm sorry. The

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reason I was confused, you didn't -- you didn't say that I used.
You want -- are you -- are you asking about any presentation that is about pelvic mesh or are you specifically saying presentations that I contributed or I presented?
Q. Given or contributed to by you.
A. And the question was, I'm sorry, did I bring?
Q. Did you bring any of those documents relating to presentations or lectures given or contributed to by you?
A. I don't -- I don't -- I don't recall that I have those in my -- I don't have an independent recollection of those being in my possession.
Q. Do you have PowerPoints relating to stress incontinence or mesh products?
A. In general or with me?
Q. In general first.
A. Yes. I have PowerPoint -- I

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have given PowerPoint presentations in the past. I do not have any with me.
Q. Could you get those for us and provide those to Mr. Snell?
A. I don't -- I don't know that I have all presentations that I've ever given.
Q. Could you provide to Mr. Snell everything that you have relating to these three areas?
A. I'm sorry, can you -- let me just -- I just want to make sure that I'm clear as far as what three areas.
Q. Pelvic mesh, pelvic organ prolapse and stress urinary incontinence.
A. Counselor, I'm sorry, can you tell me why pelvic mesh is relevant to an analysis of the -- of the TVT design? Because that's a completely different disease state.
Q. I'm not talking about the disease state. And I ask the questions. But I'm happy to answer that.
A. Yes.

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Q. The TVT uses the same material that's used in other pelvic mesh products, correct?
MR. SNELL: Objection. Overbroad.
THE WITNESS: That was not part of my analysis. My analysis was on the TVT design and safety.
BY MS. THOMPSON:
Q. But I'm asking the questions. And I'm asking you the question.
Does the TVT use the same material that's used in other pelvic mesh devices?
A. The base --
MR. SNELL: Same objection.
THE WITNESS: The base material, they're both based upon macroporous polypropylene mesh. I'm not sure I would -- and there's a wide variety of fabrication and materials used.
I don't want you to think

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that I think that, say, the mesh that we use for pelvic organ prolapse is simply the exact TVT material expanded to a larger size.
BY MS. THOMPSON:
Q. Well, let me ask you this: What is the TVT material?
A. The Gynecare TVTTM is a Amid Type I macroporous polypropylene mesh that is of a knitted design.
Q. Is it lightweight or heavyweight?
A. In my opinion, it is a lightweight mesh.
Although I would say this, weight of mesh is dependent upon the volume or surface area. And I don't really think that anybody -- excuse me, I don't think that I could classify it based on weight, given the fact that it's a 1.1 centimeter strip of material.
So the short answer is that it's lightweight. I am -- I am

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clarifying that to say that, you know, weight is a descriptor that's really based upon surface area or volume. And there's such a small volume of material that we're talking about that I don't know that anybody would specifically state that that material was of a specific weight.
Q. So it's your opinion that you can't determine whether the mesh used in the Gynecare TVTTM is heavyweight or lightweight?
MR. SNELL: Objection. Misstates.
THE WITNESS: That's not what I said.
BY MS. THOMPSON:
Q. Then -- so someone can do it but you can't, is that the answer?
MR. SNELL: Same objection.
THE WITNESS: I didn't say that either.
BY MS. THOMPSON:
Q. Okay. My question, then,

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is, is the mesh used in the Gynecare TVTTM lightweight or heavyweight; choose one of the two, or can't be determined?
A. The TVT -- the TVT device, I would consider to be a lightweight macroporous polypropylene mesh, with the understanding that mesh weight, technically, you have to consider the volume of the material.
Q. Did Ethicon show you any documents that described the TVT mesh as not being macroporous and lightweight?
A. The documentation that I am familiar with would support the -- what I have said, TVT is a lightweight macroporous mesh.
Q. And what are the documents that you're using to base that opinion on?
A. Everything that we are referencing in the report, the materials that we have included here today.
Q. Can you be more specific than that?

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A. It would take -- it would take hours to go over all of those things.
Q. Have you seen any Ethicon documents stating that the Gynecare TVTTM is large pore lightweight?
A. I -- the TVT is lightweight and large pore.
Q. And you're confident about that position?
A. Counselor, I'm extremely confident in that statement.
Q. I want to talk a little bit about your use of mesh products, including Ethicon products.
I believe in your report you stated that you began using the TVT in 1999; is that correct?
A. Yes.
Q. And were you trained by Ethicon in the use of that device?
A. I was.
Q. Do you remember who you were trained by?

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A. I do.
Q. Who is that?
A. Dr. Vince Lucente, one of my colleagues.
Q. And that training took place in early 1999; is that correct?
A. I would be guessing, but I believe it might have been in May of 1999. But I honestly can't tell you when -- when within the year it was.
Q. And was that training done formally through Ethicon or did Dr. Lucente provide a more informal preceptorship to you?
MR. SNELL: Objection. Vague.
THE WITNESS: Dr. Lucente and I are close colleagues. It is not unusual for us to communicate and get together and work together.
So, to be honest, it's -- Ethicon did not come to me and say, we want you to go work with

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Dr. Lucente. Dr. Lucente and I were having a conversation about things that he was working on. I asked if I could come up and become involved.
I'm sure that there may or may not have been a relationship, at that time, between Ethicon and Dr. Lucente regarding my training. I certainly was not aware of that directly. This is something that Dr. Lucente and I, and other colleagues, would do for each other routinely.
BY MS. THOMPSON:
Q. Sure. So you didn't attend an Ethicon sponsored training session; is that what you're saying?
MR. SNELL: Objection to form.
THE WITNESS: To the best of my recollection, there may or may not have been a presentation given. My independent

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recollection is that he and I performed maybe four or five cases together.
But I honestly can't -- I can't tell you whether there was a formal or informal -- to be honest with you, given our relationships, those lines are blurred.
BY MS. THOMPSON:
Q. Sure. And I understand.
A. Yes.
Q. I'm just trying to find out whether you were given the Ethicon oral presentation, for example, on the new device --
MR. SNELL: Objection.
BY MS. THOMPSON:
Q. -- by an Ethicon representative.
MR. SNELL: Objection. Vague.
THE WITNESS: Not to my knowledge.
BY MS. THOMPSON:

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Q. And did you participate in cadaver labs sponsored by Ethicon?
A. Note, in the next ten years, I did a tremendous amount, or a variety of different things. I'm just not clear if we're referring to that one incidence or -- I mean, this was not a one-time experience.
Q. Understood. I'm referring now to your training and I think we'll get, later, the training that you gave other doctors.
A. Right.
Q. But it sounds like, to me, and correct me if I'm wrong, you at least don't recall attending a formal training program sponsored by Ethicon --
A. No, no.
MR. SNELL: Objection. Overbroad.
BY MS. THOMPSON:
Q. -- prior to using the TVT.
MR. SNELL: Same objection.
THE WITNESS: Maybe I

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didn't -- maybe I wasn't clear.
I thought we were talking about what my first exposure was. But, of course, I had formal training from Ethicon prior to me independently performing the procedure in my practice.
What I don't recall, and I'm really don't mean to be vague, is whether I did that training first and then worked with Dr. Lucente, whether they may have -- may have simultaneously occurred, or whether I first looked at the procedure with Dr. Lucente and then had the formal training.
I do know that prior to doing the training with Dr. Lucente, I did consult with the company prior to the procedure's launch and received education at that level.
BY MS. THOMPSON:
Q. Okay. Fair enough. So

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sounds like you had both, formal training from the company --
A. Yes.
Q. -- and a preceptorship or whatever you want to call --
A. I wouldn't call it a preceptorship, but I had -- I mean, surgeons learn procedures from other surgeons.
Q. Sure.
A. Right.
Q. And do you still use the Retropubic TVT device in your practice?
A. Yes, I do.
Q. Do you use other retropubic sling products?
A. I do not.
Q. So exclusive to TVT is what you're using now for a retropubic am synthetic sling?
A. I have experience with a wide variety of devices. But if you were to come to me as a patient and we had determined that an anti-incontinence

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procedure was appropriate, then the retropubic TVT is, 95 percent of the times, the retropubic procedure or midurethral-sling-based procedure that I would use.
Q. Are you doing, currently, any transobturator slings?
A. I do do transobturator slings.
Q. What percentage of your practice, currently, is retropubic and what percentage transobturator?
A. It's probably 95 percent retropubic and about 5 percent at the present time. It has varied over time.
Q. And over the years, how many TVT or TVT Exact® products have you used?
A. By my best estimates, I would say 2,500 TVT procedures, give me a wide margin of error of probably 300 in either direction, perhaps.
Q. How do you keep track of which products you use?
A. I have a very good memory.

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Q. So if I wanted to ask you exactly how many of a given product you have used, could you tell me?
A. I could give you an approximate ballpark.
Q. And how would you do that?
A. Through a variety of methods. But, as I said, I've got a pretty good idea mentally. If you ask me how many TVT-Securs I did, I would tell you 60.
Q. And that would come from your memory, correct?
A. My memory. I'd have to go through some office records, some documentation elsewhere.
Q. So what office records would you go through?
A. We have billing data. You know, I am not telling you that these are things that are readily available to me, if you asked me, can I see this in the next, you know, hour or day.
But, certainly, there are --

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there are internal things that we could -- you know, databases that would contain such records.
Q. So you could go to your billing records and tell me whether a TVT or TVT Exact® was used?
A. No, I don't think I could do it through billing records, obviously. Billing records wouldn't tell me that.
Q. What other records would you use?
A. We would have to pull the charts on every patient. And every -- very procedure that's done carries an implant record. And so someone would sit there with approximately 2,500 charts and go through the implant records.
And by looking at the lot number or model number, we would be able to tell -- I mean, obviously, the Exacts® would all be labeled as such and the TVTs and the Obturator would be labeled as such.
Q. And is that what we would

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have to do to determine which -- what complications experienced as well?
A. No.
Q. How would we be able to determine what complications patients have experienced?
MR. SNELL: Objection. Overbroad. Are you talking about his patients?
MS. THOMPSON: Yes.
THE WITNESS: I'm sorry, what was your question? I'm not sure I understood it.
BY MS. THOMPSON:
Q. How would we determine --
A. You seem -- you seemed to have switched gears.
Q. Well, I was just interested in determining how you figured out what product was used. And I'm also interested in how you figure out what complications patients experienced.
And I'm asking you, how would we determine that?

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A. I'm sorry, that's not what you asked me originally. That's a whole -- I would have to start from scratch to --
Q. Okay.
A. You've asked me how -- you asked me what products have I used and what percentage of products that I've used and how it would be that I would determine that number of products.
Q. Yes.
Now I'm asking you, how would you determine which complications occurred with various products?
A. I would have to sit down and try and figure that out, counselor. I can't tell you off the top of my head that I have an accurate way of -- I mean, there may be ways, through the billing system, to capture certain complications based upon -- by diagnosis codes.
Q. Let's go through other Ethicon products.
Did you use the TVT-O at

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some point?
A. I did.
Q. About how many TVT-Os did you place?
A. Approximately 2 to 300.
Q. And when did you start using the TVT-O?
A. To the best of my knowledge, I can't remember when -- the product launch was in 2005 or 2002? Whenever the product was launched, roughly about when I had used the TVT-O.
Q. And how did you learn about the TVT-O?
A. By that point in time, I was -- you know, we -- we attend certain scientific meetings, publications, the usual things that we do in the course of our -- of our practice, my role reviewing manuscripts for publications, my role as an editor of journals.
I mean, there's a wide range of ways that topics like this were introduced to us.

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Q. Did you get information from sales reps?
A. On the TVT-O? Eventually. I can't tell you that that was maybe my -- if that was my first exposure or not. To be completely frank, at my level of involvement with the company, sales reps are not a -- that's not a source that I would utilize a high degree. I usually find out -- I'm educated on stuff before a sales rep is probably aware of it.
And, of course, I don't -- I'm not at liberty to discuss that with sales reps.
Q. What -- what are you not at liberty to discuss with sales reps?
A. Well, for example, if I'm involved in the -- if I've been consulted upon the design of a new product, you know, sales reps are not well versed or maybe not aware of what things are in development.
I'm just saying that most of

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the times, I'm a bit further along in that regard, and my -- you know, my -- I don't rely upon that relationship for that kind of information.
Q. What Ethicon products were you involved in the design, as you've been referring to?
A. Well, I was -- as I mentioned earlier, I was consulted on the original TVT Retropubic. I offered opinions on the Obturator product at some point in time, the TVT-Secur. I had significant involvement in the design of the TVT EXACT® product.
Q. And would these have all been prior to the devices going to market?
A. A combination. Not necessarily the same for each product.
Q. But at least for the original TVT, you were consulted before the product was marketed, I believe you said; is that correct?
A. I recall being a part of

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expert focus groups that discussed the concept that would look at towards am what was the utility, the market need, the viability.
Because I'm an educator, it's likely that I was asked questions regarding about -- about that.
Q. So at least for the sling products, you were involved in the design of the original TVT, the TVT-O, TVT-Secur and TVT EXACT®; is that correct?
A. I don't -- I don't know that I would say design in those. I was involved in the design for the TVT EXACT®.
The TVT product was already set to be launched, so, clearly, it had already been designed. I'm just saying that I had input and my opinion was sought out prior to the product being launched.
Q. For which of those products were you actually paid by Ethicon to give your opinions as to the devices?

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A. To the best of my knowledge, I provided paid consultant services on all those products.
Q. And what about Ethicon's prolapse products, were you involved in the design of any of those?
A. I mean, I had involvement in many products, some of which never saw the light of day, as well as the TVT Prolift family of products.
Q. So the PROLIFT® Anterior?
A. Correct.
Q. PROLIFT® Posterior?
A. Correct.
Q. PROLIFT® Total?
A. Yes.
Q. Do you remember the names of any of the other devices that you consulted on?
A. I could probably dredge that from my memory, yes.
Q. All right. I'll take it.
A. I believe there was a product called the V-Tac product. I

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believe there was a product called PROSIMATM product. Obviously, the PROLIFT® +M was simply a modification of the original PROLIFT® procedure.
There was a product that I was the originator of the concept, the proof of concept, the initial engineering that had to do with a post anal sling for treatment of a different pelvic floor disorder known as anal incontinence.
Q. Did that product ever have a name?
A. You know, it had a name in development. The product never came to market.
Q. What was the name in development?
A. In development, we would refer to that product as the Post-Anal Sling Surgery or PAS.
Q. And to the best of your recollection, were you a paid consultant for your involvement in each of those products as well?

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A. To the best of my knowledge, yes.
Q. Are you the type of doctor that likes to see data before using a product?
MR. SNELL: Objection. Vague.
THE WITNESS: I would characterize myself as somebody who puts a great deal of importance on sound scientific principles. Certainly, when high-quality data is available, it is given the weight that it deserves.
At different -- you know, the area of urogynecology has evolved tremendously in the past 20 years. I was very fortunate to be within this field at very early -- at a very early phase. So there are certainly procedures, techniques, theories that I was involved with very early on, and,

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obviously, data comes a little bit later.
BY MS. THOMPSON:
Q. And you actually were part of a study comparing the retropubic TVT to TVT-Secur; is that correct?
A. That is correct.
Q. Before beginning that study, did you have any data on the TVT-Secur?
A. Yes.
Q. What was that data?
A. So there was the -- as is typical, there are always safety and efficacy studies that are put before -- I'm sorry, let me rephrase that.
There was preliminary published data, I believe, from the UK or Europe about the initial design and development for the TVT-Secur. And that would have been some of the data that we were considering.
The reason for doing the trial, of course, is that we already had a procedure that was widely practiced and

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widely accepted that had a tremendous amount of data supporting its long-term safety and effectiveness.

And with a new product available, we want to specifically compare apples to apples.

Q. So it's your position that there was published literature on the safety and efficacy of the TVT-Secur before it was launched in the U.S.?

A. I don't believe that's what I said.

Q. Okay. Was there safety and efficacy -- published safety and efficacy studies on the TVT-Secur before it was launched in the U.S.?

A. I don't have independent recollection, as I sit here now, as far as the timing of one versus the other.

Q. So you don't know, one way or the other, whether there were any published data on the TVT-Secur --

A. I'm not saying --

Q. -- before it was launched?

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A. I'm not saying that I don't know. I'm just saying that as I sit here in conversing with you now, I cannot, in my mind, say, okay, the TVT-Secur was launched on this particular date and the safety -- excuse me, a clinical trial was published before or after.

Q. What did you tell the patients that enrolled in that study about the safety and effectiveness of the TVT-Secur?

A. Well, I mean, the patients underwent standardized and uniform informed consent that was the same across the entire -- the entire study. This consent was, of course, approved -- at our -- at our institution it was approved by our own internal -- our IRB.

As far as the exact language of that, I can't tell you. But, you know, essentially, we would explain to a patient that there was an established procedure that was widely practiced and was an accepted first-line therapy for

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stress incontinence and that there was a newer procedure that was FDA approved and that it was our interest in comparing the two products, looking at safety, effectiveness, differences in recovery, everything from activity, the amount of pain medication someone was to take, because we wanted to be able to independently compare the two procedures side by side in a scientific manner that would attempt to minimize bias.

Q. Did you tell patients that the TVT-Secur had never been used in a woman, prior to launching?

MR. SNELL: Objection. Foundation.

THE WITNESS: I don't recall. I don't recall that I -- that I said that, no.

BY MS. THOMPSON:

Q. Was the TVT-Secur FDA approved?

A. Yes. To the best of my knowledge, the TVT-Secur was FDA

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approved.

Q. I want to go back to your relationship with the Ethicon sales reps.

Do you recall who the sales rep was that called on you here in Philadelphia when you first began using the TVT?

A. There were several. I don't know who came first.

Q. Do you remember any of the sales reps that have called on you here in Philadelphia for Ethicon?

A. Yes.

Q. Which ones?

A. There was a woman, Eileen Ghenn. There was --

Q. I'm sorry, how do you spell Ghenn?

A. Ghenn? G-H-E-N-N, and that's a guess.

I believe there was a Marty -- I can't remember his last name. There was another gentleman whose first name was Tom. There was a woman by the

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name of Kathleen Feeney. There was, more recently, a gentleman whose name escapes me.

There were -- there were half a dozen or more. I'm sorry.

Q. And of the ones that you remember their names, can you tell me, for example, Ms. Ghenn, when did she call on you for Ethicon?

A. I honestly couldn't tell you the dates.

Q. Is she still an Ethicon sales rep and still calling on you?

A. No.

Q. And how about Marty, do you recall the time frame where he called on you as an Ethicon sales rep?

A. He was in -- he would have been in the beginning. I can't tell you that he was 1999, 2000, 2001. My recollection was within the first three or four years, I seemed to have a different rep every year.

There's another woman by the

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name of Kathy, I believe.

I'm sorry.

Q. That's okay.

And Tom, do you remember when Tom was a sales rep?

A. Counselor, I'm sorry, let me -- I can't give you specifics on any of these people.

Q. And that's fine. It's fine to say --

A. Right. I don't recall.

Q. -- I don't recall, no, or I don't remember.

And how about Ms. Feeney, do you remember when she was a sales rep?

A. To the best of my recollection, Ms. Feeney was my rep for the longest period of time. Time frame wise, it would -- I would be guessing. I would say 2005 to 2009, for example. It might have been a period of two to four years. I honestly don't know.

Q. How about currently, is there a sales rep that you're familiar

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with?

A. No, there is not.

Q. And Ms. Feeney is no longer working for Ethicon; is that correct?

A. That's correct.

Q. And Kathy, do you remember when Kathy --

A. No.

Q. -- was a sales rep?

Generally, did you have a good relationship with the sales -- Ethicon sales reps, including the ones that you mentioned?

A. Some better than others.

Q. Which ones were they better with?

A. Again, these are transient people in my life. I mean, Kathleen Feeney and I had a reasonable relationship. Eileen Ghenn and I, not so much, that I recall.

I mean, there's really nothing of any great meaning to these relationships either way.

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Q. Did you have loyalty to the sales reps?

A. No, not at all.

MR. SNELL: If you're going to move to a different topic, can we take a break?

MS. THOMPSON: Yeah, this is a good time for a break.

MR. SNELL: We've been going about an hour and-a-half.

MS. THOMPSON: Yes.

VIDEO TECHNICIAN: We are off the record. The time is 2:41 p.m.

- - -

(Whereupon, a brief recess was taken.)

- - -

VIDEO TECHNICIAN: This marks the beginning of Video Number 2. We are back on the record. The time is 3:00 p.m.

BY MS. THOMPSON:

Q. Dr. Toglia, I do have a few

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more questions about sales reps.
A. Yes.
Q. How did you typically contact the sales rep?
A. I would say most frequently they came to my office, and we would have a face-to-face discussion. I'm sure that we had e-mail contact. There was probably cell phone contact with some, when cell phones were, you know, in existence and sort of widely used to for that reason.
Q. Did you ever use sales reps' personal e-mails?
A. I used whatever e-mails they gave me. So, yes, I'm -- it's -- if they -- maybe if they e-mailed me from their personal e-mail, my reply would simply be back to them. I can't tell you that I would distinguish between the two.
Q. And what about personal cell phone numbers?
A. I honestly can't tell you whether they had company cell phones,

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personal cell phones. I gave -- again, whatever contact information might have been presented to me on a business card, I would -- I would assume -- I mean, I was assuming I was calling a business cell.
Q. Did you consider your relationship with the sales rep professional?
A. Yes.
Q. Was the relationship always appropriate with the sales reps, in your opinion?
A. Yes.
- - -
(Whereupon, Exhibit Toglia-4, 3/19/09 E-mail from Marc Toglia to Kathleen Feeney; Subject: Re: These events were approved 3.25 proctorship and 4.21 preceptorship, was marked for identification.)
- - -
BY MS. THOMPSON:

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Q. I'm going to hand you Exhibit Number 4. I'll give you a minute to look at that.
A. Okay.
MR. SNELL: What number are we on?
MS. THOMPSON: 4.
BY MS. THOMPSON:
Q. Can you describe this e-mail chain with Kathleen Feeney, one of the sales reps that you told us about earlier?
A. Uh-huh. I don't -- I can't tell you that I have -- it seems to me like there is a variety of different things being discussed over here.
Q. What were the dates of these e-mails?
A. 2009.
Q. March of 2009?
A. Yes.
Q. Beginning at the bottom of the first page?
A. Yes.

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Q. Could you just read what is contained in these e-mails between you and Ms. Feeney?
A. I'm -- she says, I am so -- and then she uses a word that I'm just not going to mention out loud -- He's nowhere from being done and wants no help.
I think she's referring to another surgeon that she was probably in a case with. I mean, there's just no context here. I'm sorry.
Q. Well, this e-mail is from you.
A. I'm sorry?
Q. This e-mail is from you on Thursday, March 19th, 10:46.
A. Okay.
I don't know -- I don't know what -- I mean, it sounds like I was -- I was scrubbed in with somebody else. I honestly couldn't tell you what this -- what the context of that was.
Q. So would you read that

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again, knowing that that's you writing the e-mail.
A. Yes. So, apparently, this says, I am so f'ed, he's nowhere being done and wants no help. You and I will be having a lunch before my case.
Q. So you're comfortable putting that word in an e-mail to the sales rep, although you're not comfortable stating the word here in this deposition; is that correct?
A. That is correct.
MR. SNELL: Objection. Argumentative.
Go ahead.
BY MS. THOMPSON:
Q. Okay. Go ahead and read the next e-mail up.
A. Call me. Pulling up now. Do you want to meet me outside in front?
Q. That's from Ms. Feeney to you?
A. Yes.
Q. And then the next one?

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A. Still have not started.
Q. And then the one after that, from Ms. Feeney?
A. Can you do her downstairs?
Q. And then the last one from you to Ms. Feeney?
A. On top?
Q. Yes.
A. The first one?
Q. Yes.
A. No, maybe, though. Your girlfriend Christine is here and won't leave. I think she liked her last suggestion too much.
Q. I don't think you read the first sentence correctly.
MR. SNELL: I'm going to object. He did read it.
MS. THOMPSON: Could you -- no. He read, no, maybe, though, your girlfriend Christine.
And it actually reads, the response to, Can you do her downstairs, is, No, maybe you,

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though.
BY MS. THOMPSON:
Q. Am I reading that correctly?
A. I don't think so. I dont know -- no. I don't -- I don't appreciate what you're implying. And I can tell you for sure that this has nothing to do with -- with that.
Q. Well, tell -- give me another explanation for why it would be No, maybe you, though, in response to, Can you do her downstairs?
A. Well --
MR. SNELL: Objection. Argumentative.
THE WITNESS: -- "do her" has nothing to do -- has nothing to do with sex, I can guarantee you that, on any level.
BY MS. THOMPSON:
Q. All right. Provide me the alternative explanation.
A. I don't have the context of what this is.

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Q. Well, these are your e-mails with Ms. Feeney.
What context do you need?
A. I don't know what she's -- I don't know what -- I mean, obviously, there was a -- there's a conversation going on that is not captured in the bulk of this -- of this discussion.
I mean, there's hours and hours that go -- they may not even be related. I mean, there's hours that are between the two.
Q. Was there other correspondence during that hours -- those hours?
A. I would have no idea.
Q. And who is Christine?
A. I think it's another -- I think it's a sales rep for -- like, a pharmaceutical sales rep or a different sales rep. I have no idea who it is.
Q. Do you think these e-mails with Ms. Feeney are appropriate?
A. I can't tell you that I

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recall -- I don't know the context. And I don't know that these are related. And I don't think that they're strung in the manner that you're insinuating.
Q. Do you think these e-mails are professional?
A. I don't think, in this line of conversation, we were discussing anything related to her -- to anything that -- I don't know. I don't know what these were referring to, to be honest with you.
Q. Did you have any personal phone calls with Ms. Feeney?
A. Yes. I mean, I'm sure that I spoke with Ms. Feeney on a variety of things. She may have told me things about her kids, she may have had ideas about job opportunities that she was interviewing for. I'm sure she asked me about friends, in terms of their health or, you know, she had a sick grandmother or something.
I mean, you know, people

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will -- as a physician, people will ask you, you know, personal questions. And, certainly, as a gynecologist, I suspect that I'm probably asked more personal questions, you know.
Q. Why did you misread that sentence when I asked you to read it?
A. Counselor, I did not misread that.
MR. SNELL: Objection. Hold on. Hold on. That's argumentative.
MS. THOMPSON: I'm just curious --
MR. SNELL: That's argumentative.
MS. THOMPSON: -- about a question.
MR. SNELL: That's argumentative.
THE WITNESS: To the best --
MR. SNELL: And your -- he's already told your insinuation is not whole --

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THE WITNESS: Right. And I don't appreciate it either.
MR. SNELL: If you're here to ask him about his opinions, why don't you do that? Unless you're trying to, like, just be totally argumentative --
MS. THOMPSON: And I didn't --
MR. SNELL: -- that's what you're doing.
MS. THOMPSON: -- insinuate anything --
MR. SNELL: Yes, you did.
MS. THOMPSON: -- or even mention sex. He did.
MR. SNELL: Yes, you did.
MS. THOMPSON: Did I anything about sex? I wanted him to read the sentence, and he left out -- it's the only thing he's misread today. I was just curious if he knew why he did that.
MR. SNELL: To the best of

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my knowledge, I read that sentence exactly.
BY MS. THOMPSON:
Q. Well, you know that you did not read it exactly, right?
MR. SNELL: Objection.
BY MS. THOMPSON:
Q. Because we read it back to you from the transcript.
MR. SNELL: Argumentative.
THE WITNESS: Counselor, let me state this clearly. I read that sentence exactly. Maybe you did not hear me read that exactly.
MS. THOMPSON: Okay. I can pursue that.
Court reporter, could you please read back Dr. Toglia's answer when I asked the question to read the e-mail from himself to Ms. Feeney at the top of the page?
MR. SNELL: I'm going to object. This is all asked and answered and covered. I'm sorry.

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MS. THOMPSON: Are you going to instruct him not to answer? He said he --
MR. SNELL: I'm not instructing him not to answer. He's told you three times.
MS. THOMPSON: Then he can answer my question that I just asked.
Amanda, if you could go ahead and read the question and answer, please.
- - -
(Whereupon, the court reporter read the following part of the record:
"Question: And then the last one from you to Ms. Feeney?
"Answer: On top?
"Question: Yes.
"Answer: The first one?
"Question: Yes.
"Answer: No, maybe, though. Your girlfriend Christine is here

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and won't leave. I think she liked your last suggestion too much.")
- - -
BY MS. THOMPSON:
Q. Is it still your position that you read that sentence -- that e-mail correctly?
A. To the best of my knowledge, I think I answered that.
Q. Okay.
A. Again, I would point out that there is -- one of these -- the initial one is 13:24 and the one above it is 19:19.
Q. Okay. You answered my question.
- - -
(Whereupon, Exhibit Toglia-5, 10/23/08 E-mail from Kathleen Toglia to Cindy Pypcznski; Subject: FDA Toglia, was marked for identification.)
- - -

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BY MS. THOMPSON:
Q. I'm going to hand you another e-mail, also with Ms. Feeney.
Can you identify this e-mail?
A. This appears to be an e-mail from Kathleen Feeney to Cindy Pypcznski.
Q. Would you go ahead and read that, please?
A. Cin, notice the totally different tone. Also note the timing of this e-mail after I had it out with him on the phone. Not regarding this, of course, as you saw. Again, please don't share this with anyone, as he is a great guy, friend and surgeon.
Q. Who is she referring to when she states that she had it out with him on the phone?
A. I don't know.
Q. But it follows an e-mail that you sent to her, correct?
A. I don't know if there was anything in between. Again, the

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difference in times is dramatic.
Q. My question is just this was --
A. It's a different date, as a matter of fact.
Q. This was provided to us as an e-mail chain.
So it does follow an e-mail that you sent to Ms. Feeney, correct?
A. I don't know.
Q. Would you please read -- what's the subject of the e-mail from Ms. Feeney to Cindy?
A. It says, FDA, Toglia.
Q. Now, if you would look at the e-mail from you to Ms. Feeney, and the subject is, Stuff.
A. Correct.
Q. And it discusses the FDA, correct?
A. Yes.
Q. And this e-mail was provided as an e-mail chain.
Would it be a reasonable

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assumption to make that it was referring to your e-mail below?
MR. SNELL: Objection. Calls for speculation. Lacks foundation. Calls for a state-of-mind opinion.
MS. THOMPSON: Are you suggesting that Ethicon produced two unrelated e-mails on the same --
MR. SNELL: No. You're asking him to speculate about what Kathleen Feeney did, sending something to somebody else with a different subject line, a whole different day later, and you're asking him to speculate that one is connected to the other; when he's already testified, asked and answered, that he can't make that connection.
MS. THOMPSON: Okay.
BY MS. THOMPSON:
Q. So you sent an e-mail to Ms.

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Feeney that was --
MS. THOMPSON: And please object to form only.
BY MS. THOMPSON:
Q. You sent an e-mail to Ms. Feeney that was -- that concerned the FDA, and Ethicon has produced an e-mail that is in the same e-mail chain that's from Ms. Feeney to Cindy, that's entitled -- it's titled, FDA Toglia.
And she says, Also note the timing of this e-mail after I had it out with him on the phone. Not regarding this, of course, as you saw. Again, please don't share with anyone, as he is a great guy friend and surgeon.
Why don't you go ahead and read the e-mail that you sent to Ms. Feeney?
MR. SNELL: I'm going to object. And move to strike what she just did. There's not even a question there.
THE WITNESS: To the best of

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my knowledge, this has absolutely nothing to do with TVT or --
BY MS. THOMPSON:
Q. I just asked you to read -- read --
A. -- or the design of TVT.
Q. Excuse me. Dr. Toglia, I just asked you --
A. Yes.
Q. -- to read your e-mail from you to Ms. Feeney.
MR. SNELL: You can read it.
THE WITNESS: Thanks for the referral. Sorry you have had such a tough week. You know I always have your back. The FDA warning is a big bummer, but I don't think it will affect you much. We will make some mild changes in how we counsel folks. It would be good if we could figure out how much of this is apogee versus other stuff. Could use it as a spin versus -- I don't know what -- gurt, or as an

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excuse to do a few informal dinners with key clients to help diffuse. I do think there is some room -- some -- there are some folks who are at higher risk for pain that it is best to avoid, hence the small drop off in our numbers. Hopefully, your company will lower your projections. I think I may blow off Chicago and just relax.
BY MS. THOMPSON:
Q. What was the FDA warning that you were referring to in this e-mail?
A. Well, it's dated 2008, so I am -- I am guessing, and it would be a pure guess that it was an FDA warning -- the first FDA safety letter that spoke about vaginal mesh kits.
Q. And in this e-mail, you felt that some mild changes in how you counseled folks would be the way to address that FDA warning?

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A. No. Because we were already addressing the FDA warning, the mild change was the fact that we would include the words, "the FDA has issued."

But we had always been, with these kits, very up front with our patients and would say, this is a newer procedure, it represents only one -- basically, everything that the FDA stated in there, we were independently doing prior to the FDA's recommendations.

The minor change would have been that we would now say that there was an FDA and we were provided that reference.

Q. Okay. And then you mention that there are some folks at higher risk for pain that's best to avoid.

Did Ethicon ever tell you that there were patients who would be high risk for pain that you should avoid the use of mesh kits?

A. I would not rely upon Ethicon to tell me that kind of stuff.

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We were -- as we sort of developed through the procedure, we both -- we both -- we both became more aware of groups of patients in whom the product was appropriate, groups of patients in whom we thought the procedure was not ideal.

And we -- you know, all surgical procedures have elemental risks --

Q. Excuse me, if you can just ask my -- answer my question, we'll move along a lot faster.

A. I'm sorry?

Q. The question was, did Ethicon tell you that there were patients at high risk for pain that should not use the kits?

A. No.

Q. Thanks.

Do you know when Ms. Feeney left Ethicon?

A. I don't know. 2009. I'm just guessing. 2011. I don't know.

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Q. Was she fired?

A. I was never told the reason why she stopped working for the company.

Q. If I told you it was in 2009, would you have any reason to disagree with that?

MR. SNELL: Objection. Foundation.

THE WITNESS: No.

BY MS. THOMPSON:

Q. I'll give you another e-mail with Ms. Feeney.

- - -

(Whereupon, Exhibit Toglia-6, 4/27/09 E-mail from Marc Toglia to Kathleen Feeney; Subject: RE: Itinerary for TVT Proctorship, was marked for identification.)

- - -

MR. SNELL: Is this 6?

MS. THOMPSON: I believe so.

THE WITNESS: Yes.

BY MS. THOMPSON:

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Q. Would you just read the top e-mail that's from you to Ms. Feeney in April of 2009?

A. I found the name for 5/28. It is Finkelstein. Sorry for this. I know it seems unimportant. I guess I'm just trying to keep myself distracted. Good luck. Regardless of what happens, you know that I think you're the best and have no questions regarding your moral integrity. Please call me afterwards.

Q. Can you tell us about the context of this e-mail?

A. I honestly have no idea what any of this refers to.

Q. So you sent Ms. Feeney an e-mail about not having questions about her moral integrity, but you can't remember what that could have referred to?

A. It's dated in 2009. She may have left the company, was leaving the company, was concerned she was leaving the company. I was just offering some --

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some support.
Q. But you don't remember anything --
A. I mean --
Q. -- more than that?
A. She could have -- she could have questioned herself or said -- you know, this may not have even been work related. She could have been having problems at home, and I was just trying to -- to reassure her.
I honestly don't. I honestly don't. I don't know who Finkelstein is. I don't know what the name applies to. I don't know what any of this is in the context of, I'm sorry.
MS. THOMPSON: We'll request any e-mails between you and Ms. Feeney on her personal e-mail.
BY MS. THOMPSON:
Q. And if Ms. Feeney gives an explanation for this e-mail, would you have any reason to -- or basis to disagree with her interpretation?

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MR. SNELL: Objection. Hold on. Calls for speculation. Lacks foundation.
MS. THOMPSON: Form is fine.
MR. SNELL: No, but I'm articulating the form, that's what it is. There's no problem with that.
MS. THOMPSON: I don't believe -- I don't think that's the case.
Yes.
BY MS. THOMPSON:
Q. Would you have any reason to disagree?
A. I -- I might. I don't -- I honestly don't know what -- what we were referring to here. These are -- these are random snippets, you know. There's no context.
Q. Well, if -- if you don't recall, then you would not be able -- have any basis to disagree with her recollection, then?

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MR. SNELL: Objection. Calls for speculation.
THE WITNESS: It's possible that her recollection may give me further information. I don't know.
BY MS. THOMPSON:
Q. When you began using the TVT in 1999, what did you provide patients, when you were getting informed consent for the use of the product, regarding risks?
A. So we were very -- I was very clear with my patients, at the time, what the traditional therapies, surgeries were, what the elemental risks were, the fact that -- that in the previous ten years there was a paradigm shift in the understanding of what caused stress incontinence, how stress incontinence might be treated differently --
Q. Dr. Toglia, I'm sorry to interrupt, but I'm just asking you what you told patients about the risks

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associated with TVT?
A. I'm telling you.
MR. SNELL: Objection. He's being responsive.
THE WITNESS: I'm telling you what that -- what that answer is.
BY MS. THOMPSON:
Q. If that's responsive, okay.
A. Okay. So in that context, we would have gone over the current -- the current available choices, we would talk, of course, first, about what was established and what was commonplace and, certainly, what my experience had been.
We would talk about the newer procedure, the preliminary experience, the theoretical benefits that might come from the newer procedure.
And I would have been very specific with them, as far as what my specific experience was, i.e., this is the third one I've done, this is the fifth one I've done.

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And also within that context, we would have said, thus far in this experience, we have seen the following outcomes.

Q. What risks did you tell the patient were associated with the TVT --

A. Sure. I'm sorry.

Q. -- device when you counseled her?

A. Sure. It's the same elemental risks. We would have talked about the risks of voiding dysfunction, the risk of possible injury to the vagina, to the bladder, to blood vessels or nerves. The theoretical risk as it relates to infection. Any risk that might be unique to the placement of -- of mesh material.

It's the same -- it's the same discussion that we had with all of the procedures that we do.

Q. What were the risks that you would have told your patient that are unique to the mesh material?

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A. In all honesty, and I'm not trying to be difficult, I can't tell you that the risks are unique. They all carry a risk of bladder injury. They all carry a risk of urethral injury.

Autologous fascial slings can erode, can have wound disruptions, which is a similar risk that, say, a midurethral sling could have.

Q. So is it your opinion that there are no risks that are unique to the mesh material contained in the TVT device?

A. I mean, obviously, exposure of synthetic mesh material, you know, as opposed to exposure of permanent suture material with the Burch, per se, as opposed to, say, exposure of the fascial slings.

Q. So the exposure is the same in all three procedures, it's just the material that's being exposed is the only difference that you can identify?

A. Say that again, please.

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Q. Is it only the difference in the material that is exposed in the vagina, not the actual fact that TVT can become exposed in the vagina?

A. Well, I think -- I think, you know, again, it's -- what we always do is we will compare one procedure to the next procedure.

So, for example, you know, a Burch procedure is done with a laparotomy, okay? There are certain risks that are more common with a laparotomy, wound infection, wound breakdown, bleeding.

There may be other risks that are a little less common with that Burch procedure.

At the time I would say, probably bladder injury was a risk that we -- in our experience, was maybe a little less common, although I think Level 1 evidence really suggests that all the risks are within in the same ballpark.

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Q. Do you get exposure of permanent suture in the vagina with a Burch procedure?

A. Yes. It's actually one of the more common things that we see.

Q. Do you get bladder erosion with a Burch procedure?

A. Yes. It's one of the more common things that we see.

Q. How common are bladder erosions with a Burch?

A. Can I refer to one of the systematic review studies?

Q. Sure.

A. So I was hoping to find a more specific -- specific number to give you, but I would say, in general, it's probably in the 3 to 4 percent range that we would see a PROLENE® suture erode into the bladder.

Q. Are PROLENE® sutures used commonly for Burch procedures?

A. Permanent sutures are used commonly --

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Q. My question is --
A. -- for Burch procedures.
Q. -- are PROLENE® suture used commonly for Burch procedures?
A. PROLENE® sutures is -- is a common choice of a suture for it, yes.
Q. Is that what you use if you're doing a Burch procedure?
A. We would either use PROLENE® or we would use ETHIBOND. We probably use them equally.
Q. And while you're at it, why don't you look for the incidence of vaginal exposure of suture with a Burch procedure?
A. To answer that question, I think I have to refer to my expert report.
Q. While you're doing that, how about urethral exposure --
A. Counselor, I'm sorry --
Q. -- with a Burch procedure.
A. -- being your typical male, I don't multitask very well. However, I

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guarantee you --
Q. All right. I will wait.
A. -- I can do two serial tasks very, very, quickly.
Q. Okay. I'm just trying to get you out of here earlier.
A. Counselor, I am -- I am at your disposal. I'm here as long as you would like me to be here.
Q. All right. That's great to hear.
MR. SNELL: She gets seven hours on the record.
THE WITNESS: You've got six hours, 15 minutes left.
Can you read me back the question again, please?
- - -
(Whereupon, the court reporter read the following part of the record:
"Question: And while you're at it, why don't you look for the incidence of vaginal exposure of

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suture with a Burch procedure?")
- - -
THE WITNESS: I recall that there was one trial where, I believe, approximately 5 percent -- I might have to find the Novara study.
MS. THOMPSON: Let's just go off the record, Greg, if you don't mind, while he looks for the studies.
VIDEO TECHNICIAN: We are off the record. The time is 3:32 p.m.
- - -
(Whereupon, a discussion off the record occurred.)
- - -
VIDEO TECHNICIAN: We are back on the video record. The time is 3:41 p.m.
THE WITNESS: Thank you. I apologize it's taking me so long.
So the first study that I

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want to reference with regard to the question of the suture erosion to the bladder is going to be the Cochrane review. This would be the Lapitan and Cody study, 2012 Cochrane review.
Data from -- and they're referencing the Albo trial.
Data from this trial showed a fivefold higher risk of having sutures pass through the bladder with open colposuspension compared to doing a pubovaginal sling procedure; perforation rate, 3 percent.
And if you'd like to go off the record again, I'm happy to find the second paper.
BY MS. THOMPSON:
Q. That's talking about intraoperative risk, correct, not erosion?
Dr. Toglia --
A. Yes? I'm sorry.

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Q. -- the passage you just read to me is talking about an intraoperative risk of passing suture through the bladder, correct?
A. Sutures passed through the bladder during open colposuspension.
Q. That's not referring to erosion into the bladder, is it?
A. No, it's not. I'm sorry.
So it wasn't suture -- it wasn't suture exposure in the bladder, was that -- was that not the question?
Q. The question was bladder erosion of suture with a Burch colposuspension.
So you'll agree that the sentence you just read doesn't have anything to do with bladder erosion?
A. Counselor, I will agree that the sentence I just read you talked about the passage of suture into the bladder.
I'm sorry if I --
Q. And that's not erosion,

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correct?
A. I'm sorry if I misunderstood your question.
MS. THOMPSON: I guess we'll go off the record again.
THE WITNESS: Thank you.
VIDEO TECHNICIAN: We are off the record. The time is 3:44 p.m.
- - -
(Whereupon, a discussion off the record occurred.)
- - -
VIDEO TECHNICIAN: We are back on the record.
THE WITNESS: Thank you. So with regard to the question of the rate of suture erosion into the bladder, it's my general recollection that there's about a 3 to 5 percent risk of suture erosion with the traditional Burch procedure when performed with PROLENE® sutures.

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BY MS. THOMPSON:
Q. And what about the risk of suture erosion into the vagina with a Burch?
A. I would say it's probably in the -- in the same ballpark.
Q. And what about suture erosion into the urethra with a Burch?
A. That should really not occur, because the Burch suspension is not placed at the level of the urethra.
Q. And it's your testimony -- but, at least as you're sitting here today, you can't give me a reference for those numbers?
A. Yes.
Q. Yes, you cannot?
A. Yes, I cannot give you a reference for those numbers. Yes.
Q. Thank you.
And is your testimony, then, that there's really no complications that are unique to the -- to a synthetic midurethral sling?

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MR. SNELL: Objection. Asked and answered.
THE WITNESS: Each procedure has risks. The majority of those risks, I would say are elemental, are common to the group. However, each procedures do have risks that are more common, perhaps, and possibly could be unique.
For example, with the poly-tetrafluoride sling, there was -- or the Ob Tape sling --
BY MS. THOMPSON:
Q. Let me clarify my question and just limit it to synthetic polypropylene slings.
A. Okay. Thank you.
So with -- with reference to the TVT Type I polypropylene sling -- I'm sorry, but I can't think of a risk that's unique to that -- to that compared to the other procedures that we do.
Q. And you'll agree with me that, in terms of significance, the

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severity of a complication is important, correct?
A. I'm not sure that I understand your question.
Q. When you're considering risks associated with a procedure, the severity of that complication is important to you as a physician, correct?
A. Can you tell me what you mean by "severity"?
Q. Well, there are minor complications and there are severe complications, right?
A. But one person's minor complication is a severe complication, and vice versa.
Could you be --
Q. Well, there are actually some definitions of the severity of complications.
But you'll agree with me that -- are you just really telling me --
A. No, counselor --
Q. -- that you don't understand

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what I mean by the severity of a complication is important?
A. I'm just not sure of the context.
So, first of all, I will agree with you that there are less severe complications and there are more severe complications with each of these anti-incontinence procedures.
Q. That was all I'm asking.
A. I'm sorry.
Q. And I wasn't even specific to --
A. Okay.
Q. -- to a device.
I was just saying, there are minor complications and severe complications, right?
A. Yes.
Q. And that makes a difference whether you're talking about a rate of minor complications or you're rating -- talking about a rate of severe complications?

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A. I'm sorry. I understand you now.
Q. Okay.
A. Yes.
Q. All right.
A. So, for example, urinary tract infection is oftentimes cited as a complication. One can argue that a urinary tract infection would be a less severe type of a complication.
Q. But a urinary tract infection with sepsis and intensive care could be a serious complication?
A. That's a good point, counselor.
Q. Thank you.
MR. SNELL: Can we take a break whenever you get right a stopping point? Because I need to use the restroom.
MS. THOMPSON: Maybe five minutes.
MR. SNELL: That's fine.
BY MS. THOMPSON:

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Q. Now, when we started this line of questioning, it's been a while, but I think we were talking about what you told your patients in 1999 --
A. Yes.
Q. -- when you first started --
A. I'm sorry, yes.
Q. -- using the TVT.
I have a little bit different question and that is now, in 2015, when you are using a retropubic TVT device, are there any additional risks or complications that you discuss with your patients, as opposed to what you did in the early years of using the device?
A. Well, now that I'm 17 years into this experience and now that I've done, let's say, well over 2,000 cases, again, I like to talk to my patients about things that might go wrong during the procedure, things that possibly could complicate their postoperative course, things that might occur during the life of that procedure.

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So to speak backwards, what we typically tell our patients these days is that, you know, over the ten-year period, subsequent to, say, having a midurethral sling -- and when I say "midurethral sling," I am referring specifically to the TVT, since that's what I perform, there's about a 3 and-a-half percent risk of having to return to the OR for something; that might include failure, that could include difficulty voiding, et cetera.

Overall, the risk that we talk to people about, in our hands, are sort of the risk of bladder injuries, about 1 percent; our mesh exposure rate is under 1 percent; our risk of voiding dysfunction is well under 1 percent; our rate of infection has been zero percent over -- over the 17-year experience; the rates of urethral injury, well under 1 percent.

And I make it a point of saying, look, just because something

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occurs very infrequently, doesn't necessarily mean that when it does occur it's not a significant complication.

Q. Are synthetic sling complications underreported in the literature, in your opinion?

A. Absolutely not. Again, we have -- we have more than 20 -- excuse me, we have at least, you know, eight to ten long-term registry studies that have followed people for at least five years. Some studies have gone out to ten years. And these are high quality, high level of evidence, of scientific papers.

And I would say, you know, ballpark figure, long-term complications are all sub 3 percent.

Q. How many deaths are reported in the literature from the TVT retropubic device?

A. And, again, I don't think that you can derive incidence or prevalence because, you know --

Q. I'm not asking for incidence

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or prevalence. I'm asking how many are reported?

A. I don't know. I would -- I would venture -- I don't know.

Q. Are you aware of any --

A. I --

Q. -- reported?

A. I'm aware of, I'm going to say, five to seven deaths.

Q. Reported in the literature, is my question?

A. Oh, reported in the literature -- I don't know how many have been reported in the literature.

Q. Are you aware of any deaths reported in the literature from the TVT device?

A. You know, when I --

Q. The question is, are you aware of any?

A. I'm just trying to explain to you, if I'm aware of five to seven I wouldn't be --

Q. I'm not asking you how many

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you think have occurred --

A. Right.

Q. -- I'm asking you how many have been reported in the literature?

A. In my reading of the literature, I'm saying that I am aware of about five to seven. I'm just saying that I cannot produce to you what -- in what form or publication they would have been.

Q. And how many do you think have actually occurred?

A. I don't know, counselor.

Q. So you think there are five to seven deaths reported in the literature from TVT?

A. That's the best of my recollection. But I will tell you that I'm not aware of any personally.

Q. Do you tell your patients that polypropylene degrades in the human body?

A. There is no high-quality evidence that suggests that polypropylene

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degrades in the body.
Q. What does degradation mean to you?
A. Well, again, and I looked this up. It just -- it depends. And the definition varies.
Degradation is -- to me, means a loss of structural integrity, a loss of function.
You can certainly degrade one's morality, that's a different mention, that's obviously not applicable within the setting of the mesh.
Q. Okay. And it's your opinion that there's no high-quality study that shows -- that mesh degrades?
A. I'm quite certain that there is no high-quality studies that would suggest that the mesh degrades. It is certainly inconsistent with the body of Level 1 evidence and the long-term registration studies.
Q. Is there high-quality evidence, in your opinion, that states

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that mesh does not degrade?
A. Well, I don't know how we would know that, counselor, because we don't routinely explant mesh that is behaving properly in the body.
Q. Does mesh that's not behaving properly in the body degrade?
A. Again, I'm not aware of any high-quality data. I can tell you that -- the data is very, very clear and very reassuring that there are no clinical concerns that that phenomenon exists.
Q. That's not my question. I'm not talking clinically.
A. Yes.
Q. I'm talking about, and I would --
A. Degrading in the body is a clinically-based question.
Q. No. I'm talking about degradation, not clinical.
A. Okay.
Q. But you mentioned the

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structural composition of the polypropylene.
MR. SNELL: I'm going to object. That misstates. He said structural -- well, the record will be clear what he said. And I think he was responsive with regard to how he defines degradation.
BY MS. THOMPSON:
Q. Okay. I'm going to -- I'm going to define degradation in the chemical sense, and that is a change in the chemical structure of the compound.
A. Okay.
Q. Are there any studies in the literature that tell you that that does not happen with the TVT mesh when placed in a woman's body?
A. Can I ask you to restate that without the double negative, please?
Q. Well, you told me there are no high-quality studies that state that it degrades. I don't know how to do that

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without the negative.
Are there any studies that show you that it does not degrade?
A. The study by Falconer, which I believe was published in 2001, where they did, in fact, go back and take site specific biopsies showed no degradation in the material.
Q. Now, were they looking at that from a chemical composition standpoint?
A. Again, if you would like to give me a minute to locate that study.
MS. THOMPSON: Okay. We'll go off the record.
VIDEO TECHNICIAN: We are off the record. The time is 3:58 p.m.
- - -
(Whereupon, a discussion off the record occurred.)
- - -
VIDEO TECHNICIAN: We are back on the video record.

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THE WITNESS: Read me the question one more time, please?

- - -

(Whereupon, the court reporter read the following part of the record:

"Question: Now, were they looking at that from a chemical composition standpoint?")

- - -

THE WITNESS: So, no. The Falconer study was looking at it from a histologic standpoint. I'm not aware of any concerns that there might be degradation that would prompt one to do those kinds of studies.

BY MS. THOMPSON:

Q. And that study also was biopsying the tissue around the mesh product, not the mesh itself, correct?

A. You are correct, counselor.

Q. So you're not aware of any studies, then, that demonstrates that

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polypropylene mesh does -- or TVT mesh does not degrade in the female body?

MR. SNELL: Objection. Asked and answered.

MS. THOMPSON: Well, he said he would look and he found Falconer, which doesn't apply, so I'm asking if he has any others.

MR. SNELL: I'm going to object. That's also vague. You asked him specifically, in the last question, about chemical degradation. And now you said degradation. He already said he doesn't think degradation occurs, and he's told you all the reasons why.

MS. THOMPSON: All right. Fair enough. I'll ask it -- I'll ask again with chemical degradation.

BY MS. THOMPSON:

Q. Are you aware of any studies, then, that demonstrate that

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chemical degradation does not occur with polypropylene mesh implanted in the body?

A. I think that the long-term registry trials and the significant lack of chronic problems suggests that there is no chemical degradation of the material.

I'm also -- I'm a little bit -- what does it matter if the material degrades if the person is still continent? You know, it's not that are -- we're suspending somebody from a bridge from this material and that loss of the material would compromise that person's position.

The procedure is designed to reestablish urethral stability, and it does so effectively in studies that have gone up to 17 years.

Q. So is it your opinion that degradation -- chemical degradation of the material doesn't matter if the woman is still continent?

A. Well, and, again, I'm

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certainly not trying to be difficult, but I'm not certain what you mean by "chemical degradation," what specifically, what we're looking at, we're changing in, we're talking about isomeric change in the compound? We're talking about racemic change in the compound? We're talking about nephelation of the compound? What -- what specifically is implied with the term "chemical degradation"?

Q. You're not a chemist, right?

A. I have a degree in biochemistry. I have done chemical research.

Q. But you don't consider yourself a chemist?

MR. SNELL: Objection.

THE WITNESS: I think I just told you what my --

BY MS. THOMPSON:

Q. So you are a chemist?

A. What's that? I --

Q. You do consider yourself an

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expert in chemistry?
A. Those are different questions.
Q. Do you consider yourself an expert in chemistry?
A. I would consider myself an expert in chemistry, yes.
Q. And -- but you're not familiar -- are you familiar with the term "oxidation"?
A. Of course.
Q. Are you familiar with the term "oxidative degradation"?
A. Yes.
Q. Let's just use oxidative degradation, then, maybe we can --
A. Fair enough.
Q. -- get on the same page here.
A. Sure.
Q. Are you aware of any studies that show that oxidative degradation does not occur with polypropylene mesh placed in the body?

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A. There are no high-quality evidence studies that suggest that it does occur. Therefore, my inference would be that it does not occur.
Q. What does oxidative degradation mean to you?
A. Oxidative degradation is the process in which oxygen comes in and will alter the composition; so, you know, you've got nitrous oxide it becomes nitric oxide.
Q. What happens when polypropylene undergoes oxidative degradation?
MR. SNELL: Objection. It lacks foundation. He's told you he doesn't believe it does.
BY MS. THOMPSON:
Q. So is it your opinion that polypropylene does not undergo oxidative degradation in vitro or in vivo?
A. I'm speaking in vivo; I'm not aware of any high-quality evidence that would suggest that polypropylene

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mesh, within the context of the TVT device and its intended use to treat stress incontinence in women, which was the subject that I was asked to research and form an opinion, undergoes oxidative degradation.
Q. Are you a materials expert?
A. I certainly am a materials expert, yes. At least --
Q. Are you a polymer expert?
A. I have a better than average, and some would consider to be an expert understanding, of polymer medicine as it relates to my subspecialty field, yes.
Q. Is it your opinion -- well, let me ask you this: What additives go into the mesh that the TVT is comprised of?
A. Can you be more specific?
Q. What additives are added to the polypropylene resin that makes up the TVT?
A. I mean, there's an enormous

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amount --
Q. If you don't know, it's fine. Just say you don't know.
What additives go into the mesh -- to the resin that forms the TVT mesh?
A. I'm not sure I know what you're referring to, in terms of adding oxygen goes into it.
Q. Is the polypropylene that's used in the TVT mesh pure polypropylene?
A. Well, no. Polypropylene itself is not a pure molecule. I mean, there are --
Q. What is added to the polypropylene or is nothing added or do you not know?
A. I can't tell you off the top of my head all of the different compounds that would go into the -- you know, the creation and the extrusion of polypropylene.
Q. Did you ever ask anyone at Ethicon what was in the polypropylene?

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A. I did not ask anybody at Ethicon what was in polypropylene.
But that shouldn't imply that I did not read about polypropylene mesh or the base PROLENE® material. These are materials that we have used extensively in the last 40 to 50 years in the area of surgery.
Q. Did Ethicon tell you that its own studies on PROLENE® suture shows that it degrades?
MR. SNELL: Objection. Misstates. Lacks foundation.
THE WITNESS: I would not rely upon Ethicon to tell me such things.
And, again, this is within the context of the TVT design, I'm not aware of -- you know, the animal studies really are not relevant. We have Level 1 evidence to support the long-term safety of these things --
BY MS. THOMPSON:

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Q. I'm not talking about -- if we can get away from the long-term safety. I'm not discussing the long-term safety. I'm discussing the material itself.
A. Yes.
Q. If Ethicon has information that the material degrades in the human body, is that something that you, as a doctor, would want to know about?
MR. SNELL: Objection. Lacks foundation.
Go ahead.
THE WITNESS: I would not be dependent upon Ethicon --
BY MS. THOMPSON:
Q. I didn't ask you --
A. -- for that information.
Q. -- if you depended on it.
Is that something that you would like to know, if Ethicon has information that their product degrades, is that something you would want to know, as a physician?

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MR. SNELL: Objection. Lacks foundation. Misstates evidence.
THE WITNESS: No, it is not.
BY MS. THOMPSON:
Q. It's not something that you would want to know?
A. I would not want to know it from Ethicon, no.
Q. Who would you know it from?
A. Would I know what from?
Q. Who is going to tell you that Ethicon mesh degrades if it's not Ethicon?
MR. SNELL: Objection. Hypothetical. Calls for speculation.
MS. THOMPSON: Well, he brought it up. He didn't want to hear it from Ethicon.
BY MS. THOMPSON:
Q. I'm asking you, who else would you want to hear it from?
MR. SNELL: You asked him

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the question. He's already told you he doesn't think it degrades. I don't know -- I don't understand what you're doing.
BY MS. THOMPSON:
Q. I'm saying if Ethicon has knowledge that it degrades, is that something you want to know?
MR. SNELL: He's already -- objection. Asked and answered three times.
MS. THOMPSON: Okay. I thought maybe he would change his opinion on that.
BY MS. THOMPSON:
Q. Would patients want to know if the material, the plastic that they're putting in their bodies, degrades?
MR. SNELL: Objection. Calls for speculation.
THE WITNESS: I think the only thing the patients would want to know is whether or not the procedure worked long-term for

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them.
BY MS. THOMPSON:
Q. Okay. So, to you, if the procedure works, it doesn't really matter whether that material degrades or not?
A. Absolutely.
Q. All right.
A. It does not matter to me.
Q. Thank you.
MS. THOMPSON: We'll take a break.
VIDEO TECHNICIAN: We are off the record. The time is 4:11 p.m.
- - -
(Whereupon, a brief recess was taken.)
- - -
VIDEO TECHNICIAN: This marks the beginning of Video Number 3. We are back on the record. The time is 4:38 p.m.
BY MS. THOMPSON:
Q. Dr. Toglia, when we went on

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our break, I was asking you about what you tell your patients now about polypropylene mesh and the TVT device.
Do you remember that?
A. Yes.
Q. Do you tell your patients that polypropylene mesh creates a chronic foreign body reaction in the body?
A. I don't tell them that, because there is no evidence that it causes a chronic foreign body -- counsel, I'm sorry, it's staring right in front of me here. I did address your question about oxidation --
Q. I didn't ask you any other questions, so Mr. Snell can ask you about that later.
A. Okay. Thank you.
Q. So it's your opinion that polypropylene mesh does not create a foreign body reaction in the body?
A. My experience, in using polypropylene over the last 17 years, I have never seen an incidence -- an

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instance in which polypropylene mesh caused a chronic foreign body reaction.
I feel that that is very consistent with the long-term registries trials --
Q. Okay.
A. -- that it focused on the safety and looked specifically for that kind of problem.
Q. Do you -- if Ethicon had information that the mesh used in the TVT creates a chronic ongoing foreign body reaction, is that information that you would want to know?
MR. SNELL: Objection. Lacks foundation.
THE WITNESS: As a general rule of thumb, I am not dependent upon Ethicon to provide me with any such information.
BY MS. THOMPSON:
Q. Is it information that your patients would want to know?
A. I honestly don't believe

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that they would care to know.
Q. Do you tell your patients that polypropylene mesh shrinks up to 30 percent?
A. I believe -- well, the discussion is that -- and, again, within the context of the TVT sling, as it was used for stress incontinence, I don't believe that would -- that small amount of lightweight macroporous material, that clinically there is a relevant amount of shrinkage.
In the context of other discussions with other base procedures, there is a discussion that has to do with changes in the mesh, as you stated, but not for TVT sling, no.
Q. So the answer is, no, that you don't tell your patients about shrinkage of the TVT sling?
MR. SNELL: Objection. Misstates.
MS. THOMPSON: Will you stop the speaking objections? Just say

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object, and without --
MR. SNELL: No. No. I'm allowed to state the objection to form. That is a form objection. Misstates.
MS. THOMPSON: Objection to form. You can't go into all the other stuff that you've been doing.
BY MS. THOMPSON:
Q. Go ahead and answer the question, Dr. Toglia.
A. It's my -- it's my expert opinion that the TVT mesh does not, in fact, shrink in vivo.
Q. Do you tell your patients about the possibility of chronic pain syndromes?
MR. SNELL: Hold on. Objection. Form.
MS. THOMPSON: You can answer, though.
MR. SNELL: Go ahead.
THE WITNESS: In the 17

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years that I have been implanting the TVT mesh for the indication of stress incontinence, in over 2,500 patients, let's say, I have never once seen chronic pain syndrome arise from the retropubic TVT sling that we are discussing today.
BY MS. THOMPSON:
Q. So you're saying you have never, not one single patient, have you seen a chronic pain syndrome related to the retropubic TVT?
A. That's what I said.
Q. And how would you know?
A. We -- now, my practice is in suburban Philadelphia, we have very high rates of follow-up. Patients are seen on a regular basis. They are -- they will contact us with problems. We tend to see the problems.
Q. When do you see your patient for a postoperative checkup after a TVT?
A. Well, there are a series of

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evaluations that we'll see them for. The first one is always within the first four months or so -- excuse me, within the first four weeks or so.
Usually, there's a second follow-up within three months or so.
Subsequent to that, it may be six or 12 months.
Again, you know, stress incontinence, unfortunately, rarely happens in isolation. These are patients that have chronic pelvic floor disorders. I would say, in a large number of our cases, we continue to see those patients annually.
Those patients that, at some point -- or, let's say, as you said earlier, were cured of their problem are told that they are welcome to come back with any concern that they might have.
Q. What is your rate of follow-up with patients who receive a TVT sling.
A. Our rate of follow-up is

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above the 90 percentile.
Q. What do you mean by "90 percentile"?
A. Excuse me, I apologize. 90 percent or higher.
Q. And how is that determined?
A. Because we have records and we follow-up with patients after surgery to make sure that they come in for their scheduled visits.
And the ones that don't, that fall through, typically are contacted.
Q. At what point?
A. As I mentioned to you, I think I described for you the parameters for our follow-up.
So if somebody -- I mean, obviously, there are -- you know, people go on vacation, have to take care of a loved one. So if they are not seen, say, at that four-week mark, they're asked to follow up with -- they are scheduled for an appointment, say, within that

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three-month period of time.
Q. So if I requested documentation of your rate of follow-up on your patients who receive TVT devices, could you provide that to me?
MR. SNELL: Objection. We are not producing any of his clinical records or charts, nor have you produced any such thing like that.
Your experts --
MS. THOMPSON: I didn't ask for clinical records and charts. I asked him, could he provide it.
And you can answer the question.
And that's a speaking objection.
BY MS. THOMPSON:
Q. Go ahead, Dr. Toglia.
A. I personally --
MR. SNELL: Actually, I'm objecting and saying that will not be produced. I'm putting that on

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the record.
MS. THOMPSON: I didn't ask for production, did I?
BY MS. THOMPSON:
Q. Go ahead and answer, Dr. Toglia.
Could you provide it if I ask for it?
A. I would not provide that.
Q. That wasn't my question.
Could it be provided?
You've already testified that you don't even know how to keep track of what procedures are done --
A. I disagree with you, counselor. I told you -- I gave you specific examples --
Q. The record speaks for itself.
A. -- of how --
MR. SNELL: Don't cut him off. He's telling you -- because you just -- you just threw an insult at him.

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Go ahead and finish telling her.
THE WITNESS: Counselor, you asked --
MS. THOMPSON: And that's a speaking objection.
THE WITNESS: Counselor, you asked me the type of follow-up we have and you specifically asked me what do we do in the situation if someone were to not follow up.
And I gave you a very specific answer that the patients are contacted. And, oftentimes, they are contacted by myself.
BY MS. THOMPSON:
Q. Dr. Toglia, if you would try to listen closely to my question, because a lot of your answers, I'm -- I'm sorry I'm losing my patience, are not the answer to the question that I'm asking. So if you just try to listen, we'll get out a lot quicker, okay?
A. I don't always understand

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what it is that you're asking.
Q. Let's make it clear from this point forward, if you don't understand my question, will you ask me to repeat it or rephrase, but not answer a different question, okay?
MR. SNELL: And I'm going to object to counsel's statement. I think the witness has been responsive. She just doesn't like his answers. That's my position.
MS. THOMPSON: I'm loving his answers. That's fine.
BY MS. THOMPSON:
Q. My question is, I asked you about your rate of follow-up --
A. Correct.
Q. -- and you said it was above the 90 percent mark.
And I'm asking you, is that something that could be provided, if I requested it?
A. It is probably something that could be provided.

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Q. And what records would you rely on to produce that?
A. We have medical records within the practice on all of our patients.
Q. So someone would have to go through each record to determine when the patient last saw you, when she was contacted, what problems she was having, correct?
A. That is correct.
Q. Okay. And are you aware of literature that shows that most patients with mesh complications do not return to the original doctor who implanted the mesh product?
MR. SNELL: Objection. Form. Foundation.
THE WITNESS: I'm aware of literature that would speak to the opposite.
BY MS. THOMPSON:
Q. And what is that literature? If you could tell me, please.

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A. Well, the first study, off the top of my head, I believe was the Abbott study, in which they commented, in the conclusions, that most people did return to their -- to their original provider initially.
And I would say that, regardless, that would be highly atypical for my practice.
Q. How do you know that?
A. Because we have a rate of follow-up that is over 90 percent.
Q. That if you went back and looked at every chart of every patient you've seen, you could determine whether that's true or not?
MR. SNELL: Objection. Misstates.
BY MS. THOMPSON:
Q. You can answer it.
A. I thought that I already answered the question, I'm sorry.
MR. SNELL: You did.
BY MS. THOMPSON:

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Q. You can answer it again.
MR. SNELL: Objection. Asked and answered.
THE WITNESS: Can I ask that they simply read my answer back?
MR. SNELL: Yes, you may.
- - -
(Whereupon, the court reporter read the following part of the record:
"Question: And what records would you rely on to produce that?
"Answer: We have medical records within the practice on all of our patients.
"Question: So someone would have to go through each record to determine when the patient last saw you, when she was contacted, what problems she was having, correct?
"Answer: That is correct.")
- - -
BY MS. THOMPSON:

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Q. Do you continue to follow up on patients who have left your practice, one, two, three, four, five, six, seven, eight, nine, ten years after the procedure?
A. If they've left our practice, we would have no access to that.
But, as I've stated earlier --
Q. You don't need to state things that you've said earlier.
So if a patient has left your practice because, say, they were cured of their stress incontinence at their follow-up visit, that's not a patient that you would continue to contact on a regular basis, is it?
MR. SNELL: Form.
THE WITNESS: So at the point of time, let's say that a patient was cured, I always offer to the patient that since we've done a surgical procedure that

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involves a permanent implant, that it is my advice that they continue to follow-up with us annually or whether they -- any time that they have a concern.

I also let them know that I'm not going to harass them into follow-up if they feel that they are doing well.

Initially, we saw all of our patients annually. And after about five, six, seven years, patients would literally say, Doctor, can I say something to you? I don't know why I have to continue to come, I'm fine, it costs me a co-pay to get here, I have to take time off work.

BY MS. THOMPSON:

Q. So the answer to my question, again --

A. Yes.

Q. -- is that you don't contact patients after they've left your

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practice, correct?

MR. SNELL: Objection to form. Asked and answered.

MS. THOMPSON: He didn't answer my question, Burt.

MR. SNELL: You're asking the same question ten times. He's already told you all the different things that can happen.

BY MS. THOMPSON:

Q. Do you contact your patients after they've left your practice or not?

MR. SNELL: Same objections.

THE WITNESS: I'll say the same thing I said previously.

If a patient leaves our practice, and by "leaves our practice," means she informs us that she is no longer requiring our services, it would not be appropriate for us to contact that patient.

BY MS. THOMPSON:

Q. All right. Could you pull

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the Abbott study that you referred to that said strictly the opposite of what I said, that most patients don't return to their original implanting surgeon and show me in that article what you're referring to?

A. I don't think I used the word "strictly."

MS. THOMPSON: We can go off the record, please.

VIDEO TECHNICIAN: We are off the record. The time is 4:51 p.m.

- - -

(Whereupon, a discussion off the record occurred.)

- - -

VIDEO TECHNICIAN: We are back on the video record. The time is 4:54 p.m.

THE WITNESS: So I just want to clarify if I understand you correctly.

So what you asked me was

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whether or not -- you asked me whether there was evidence that patients that had a mesh complication were unlikely to return to their original provider?

BY MS. THOMPSON:

Q. I think what I said was the majority of patients with mesh complications do not return to their original implanting doctor.

A. Okay. So I will correct myself.

The Abbott study is not the correct study to look at. I mis -- misremembered, if that's a word, that the Abbott study, the majority -- or half the patients have come from an outside system.

I will -- I will now refer to the registry trials, if you'll -- and there are several --

Q. I'm not talking about a patient that's in a trial.

A. No. Excuse me. Excuse me.

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I will -- when I say trial --
MR. SNELL: Don't interrupt him when he's answering.
THE WITNESS: -- I mean study.
So there are -- there are -- within the close -- excuse me.
Within closed healthcare systems, an example would be Kaiser, and the other would be the healthcare systems of, say, Finland and Austria, within those closed systems, they would be able to capture -- and Canada would be -- would be another example, they would be able to capture that patient in the system no matter where they ended up within the system.
BY MS. THOMPSON:
Q. Are you in Kaiser?
A. I am not a Kaiser physician.
Q. Are you in Finland?
A. No, I'm not in Finland.

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Q. Are you in Austria?
A. No.
Q. Are you in Canada?
A. No.
Q. Thank you.
A. But that's not the question that you asked me.
Q. You've answered my question.
A. I'm trying to answer the question, and you're trying to prevent me from answering.
Q. What question is on the table?
A. You asked me whether or not it is true that most patients who experience a complication are not then seen within the same system. And I'm telling you that in those circumstances, of which there is abundant data, some data that goes out to ten years, that that is not a correct statement. Those patients are captured.
So, for example, if you're in Finland or Austria and you had a sling

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complication, that -- and you sought medical treatment, those are captured to a high degree of specificity.
Q. And that's not responsive to any question I asked. So we'll move on.
MR. SNELL: Move to strike. I think it was totally responsive to the question.
BY MS. THOMPSON:
Q. Do you tell your patients that if they have complications that require a removal of the sling, that there may be multiple surgeries to correct that?
MR. SNELL: I'm sorry, can you repeat that back?
BY MS. THOMPSON:
Q. Do you tell your patients that removal -- if they have complications that require removal of the device, it may take multiple surgeries to correct it?
A. That is -- that is such a highly -- in my practice and experience,

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that is such a highly unlikely occurrence, that that would not -- I would not speak to something that has that low of an occurrence.
I would have difficulty thinking of a patient that underwent a TVT sling for the intended purpose of stress incontinence that would have required multiple procedures for that one sole thing.
And in that regard, I would speak to the Abbott study, in which they acknowledge that for just sling-related procedures, typical management of medical complications were medical and not surgical and that, in general, were more easily -- easier resolved.
Q. Easier -- more easily resolved than POP mesh?
A. Correct. But --
Q. Can you show me where in Abbott it tells it -- tells you that most of them are medically managed?
A. Okay. Back to the Abbott

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study, on Page 163, last couple column. Additionally, those women with complications after sling-only procedures were treated more often with medical management and rarely required surgical re-intervention.

Going --

Q. That's comparing --

A. Going --

Q. That's comparing to the prolapse mesh patients?

A. That was the objective of the Abbott trial.

Second point, at the top of that page. The treatment of stress incontinence has a more predictable and less severe course of complications compared with that of synthetic mesh that is used in the management of pelvic organ prolapse.

Q. Correct, comparatively speaking.

And the conclusion of the study, just to clarify is, Most of the

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women who seek management of synthetic mesh complication after POP or SUI surgery have severe complications that require surgical intervention. A significant proportion require greater than one surgical procedure.

Did I read the conclusions to that study correctly?

A. My apologies, I wasn't following you. Where -- can you tell me what page you're speaking to?

Q. The first page, the conclusions of the study. Did I read it correctly? That's the only question I have for you.

A. The comment?

Q. The first page of the study, under conclusions, did I read that correctly?

A. Counselor, I'm trying not to be difficult, but there's not a -- there's not a subtitle that starts with conclusions.

Q. In the abstract, it has,

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objectives, study design, results and conclusion on the first page.

A. The pattern of complaints differed by the index of procedure.

I mean, I think, you know, you're taking --

Q. Most of the women --

A. You're taking it out of --

Q. Did I read it correctly? Did I read the conclusions correctly? That's the only question on the table.

A. The conclusions --

MR. SNELL: I'm going to object to the form.

THE WITNESS: The conclusions are what are listed under the comment, that's the conclusion.

BY MS. THOMPSON:

Q. I didn't ask you -- I asked you, did I read --

A. You're reading the abstract. You're reading an abstracted sentence.

Q. So you cannot answer the

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question --

A. I did answer the question.

Q. -- whether I read it correctly or not?

A. I'm reading it under the conclusion of the paper, okay? It's right here. Additionally, those women with complications after sling-only. We are talking --

Q. Okay. Let's move --

A. -- about standalone sling procedures --

Q. Let's move on.

A. -- correct?

Q. Let's move on.

Do you tell your patients that the polypropylene mesh and TVT device creates chronic inflammation?

MR. SNELL: Objection. Asked and answered.

MS. THOMPSON: No, I asked about chronic foreign body reaction. Those are two different things.

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MR. SNELL: I stand corrected. I thought you said that.

THE WITNESS: Based upon our experience in the last 17 years, with nearly 2,500 procedures, we have not observed any chronic inflammation as it relates to the retropubic TVT, and, therefore, we don't speak to them about something that we have not seen.

BY MS. THOMPSON:

Q. If Ethicon had information about chronic inflammation, is that something that you, as a doctor, would want to know?

A. As an expert in this field, I would not rely upon Ethicon for that information. I seek that information myself, formulating that opinion from high-quality studies.

Q. Is that information patients would want to know?

A. I think patients would --

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would love to know that I spend the time seeking out high-quality data and look at long-term studies and rely upon those type of systematic review groups when I present the safety profile of that procedure.

Q. Do any of your patients have complications after a TVT procedure?

A. Patients can have complications after any surgical procedure.

Q. That wasn't my question.

Have any of your patients had complications after a TVT procedure that you've performed?

A. Yes. As I've stated in my --

Q. Okay. That's -- that's all I need.

And what are those complications?

A. The most common complication that we see would be injury of the bladder, which, in our hands, is about 1

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percent.

Q. What else?

A. I believe that we did discuss this earlier on, but it was specific to myself.

There's always a risk of bleeding, that is something that is discussed with all patients. We tell them about our experience with bleeding, that we see it a little more commonly in the younger patients.

We talk about the potential risk that, maybe, the symptom improvement may not be as much as they want and that there are occasions where a second procedure might need to be performed.

Conversely, we tell people that there is a small risk for voiding dysfunction and that, at times, that will require re-intervention for that reason.

There is a risk for vaginal perforation, urethral perforation, nerve injury, bowel injury. And those are all discussed with the patients.

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We speak about other risks such as pain with sexual intercourse, more specifically, relative to the other procedures, and that in our experience, and according to high-quality data, the rate of dyspareunia is exceedingly low with the retropubic TVT sling.

Q. Is it your opinion that when complications occur it's because the surgeon placed the device improperly?

A. I would say, in most cases, it is a direct result of -- it's user dependent, and I make that point in my paper, in my --

Q. And that would include the complications that you've had with your procedures?

A. Correct.

Q. And how many TVT devices have you removed or performed some kind of revision surgery on?

A. I think it's best to answer that sort of on an annual basis. Again, understanding that I've been performing

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this procedure over a 17-year period of time.
I would say, in the average year, that probably ranges from zero to one.
Q. So only zero to one time per year are you doing any corrective surgery on a TVT device?
MR. SNELL: Objection. Misstates.
BY MS. THOMPSON:
Q. Zero to one per year --
MR. SNELL: You're changing your question. You're asking about TVT Retropubic and then the next question is a TVT device, which can be --
MS. THOMPSON: Sorry. I'll rephrase it.
And, again, if you'll just ask me if you don't understand a question.
THE WITNESS: I understand.
MS. THOMPSON: Then you can

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object to form. He can ask me if he doesn't understand it.
THE WITNESS: I'm listening to what you're asking.
MS. THOMPSON: Because I think you knew -- I think you knew what I meant when I said that.
BY MS. THOMPSON:
Q. So zero to one TVT Retropubic devices are how many you are removing in a typical year; is that correct?
A. Well, I don't think that you're accurate, the word "removal." It's removal or revision.
I would say that probably once a year, or so, are we having to surgically revise a TVT device -- excuse me, a TVT procedure.
And I'm -- again, for the I remember sake of argument, I'm speaking about the retropubic TVT procedure that we are doing for stress incontinence.
Q. In your report, you said

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that you are considered one of the leading experts in the Greater Philadelphia region on surgical revision of complications related to vaginal mesh procedures.
Is that a true -- true statement?
A. That is a true statement.
Q. And why is there a need for experts on surgical revision of complications related to vaginal mesh procedures?
A. I think there are experts required for the management of any kind of surgical revision of problems that can occur.
Q. Now, I've never seen someone say that they are an expert in the surgical management of complications related to a Burch or to autologous fascial sling or to native tissue repairs.
Explain to me why an expert is needed for the management of vaginal

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mesh complications.
MR. SNELL: Objection. Form.
THE WITNESS: In that context, I would hold myself out in those fields. The -- the need to re-intervene is identical, practically speaking, amongst the three most common anti-incontinence procedure, whether that be a Burch -- I probably revise more Burches, fascial slings, bladder neck slings than I do midurethral slings.
BY MS. THOMPSON:
Q. So what you intended to say is that you're one of the leading experts on surgical revisions of complications for any pelvic procedures, not vaginal mesh procedures?
A. I don't -- pelvic procedures is a little bit too broad.
With regard to prior

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surgical intervention for pelvic floor -- surgery for pelvic floor dysfunction, I probably have as much experience as anyone else in the area. And that is a frequent source for referral.

Q. You, I believe, said in your report that you had done 3,000 patients with TVT, but that may have been all urethral slings, it doesn't make too much --

A. I think --

Q. -- difference for my question.

A. Well, I think 3,000 may refer to everything, including sacrocolpopexy performed with mesh. I think it's 3,000 mesh related procedures. That would include the entire scope.

Q. Okay.

A. If you just want to accept me at my word, I think that's -- I'm pretty --

Q. We'll go ahead and find it.

A. That one I'm pretty sure of,

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because I said it.

Q. Well, whatever it is, it's in your report. We can look it up later.

You said in those 3,000 patients --

MR. SNELL: Where are you at, counsel? Just so --

MS. THOMPSON: Okay. I'll have to find it. I thought I had it underlined.

THE WITNESS: I don't think I said anything beyond the fact that I had experience in 3,000 patients. I don't think I went -- I did not go on.

BY MS. THOMPSON:

Q. On Page 9, the last sentence. I have personally used it -- and I think that's referring to polypropylene mesh, I guess?

A. That would be correct.

Q. -- as my primary implant material in my patients for over 15 years in more than 3,000 patients --

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A. That is correct.

Q. -- and have yet to observe a single case -- now I want to go through some of these.

How do you define -- define "mesh rejection"?

A. Since I haven't seen a case of that, a case in which there was overt expulsion of the mesh, in which there was complete failure of primary healing, in which there was systemic response of an inflammatory reaction.

Q. So your definition of rejection, then, is overt expulsion and not -- that would not include erosion into any organ, correct?

A. My definition is just, succinctly, would be evidence of overt graft versus host disease.

Q. And what symptoms would the patient present with --

A. Excuse me, host versus graft.

Q. I knew what you meant.

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What symptoms would the patient present with, in your opinion?

A. There could be expulsion of the material, there could be complete failure of primary healing, recurrent -- or some kind of systemic response, anaphylaxis.

Q. And by "overt expulsion" you are not referring to erosion into the vagina, the urethra or bladder?

A. Thank you for clarifying that.

So rejection is rejection, exposure is a different phenomenon, correct.

Q. And what testing did you do on those 3,000 patients to determine there wasn't a host versus graft condition?

A. I don't think it would be ethical, counselor, for me to test -- test -- somehow subject a test on an asymptomatic patient. And I think that a large body of the literature cited by

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your experts speak to the fact that they were unable to do that kind of testing because of ethical considerations.
Q. You would agree with me, though, that rejection is an immunologic response to a foreign body?
A. I think --
MR. SNELL: Objection to form.
Go ahead.
THE WITNESS: I think that's one -- one type of rejection might be immunologic, yes.
BY MS. THOMPSON:
Q. And are you aware of literature that tested, immunologically and/or histologically, for a rejection condition?
MR. SNELL: Objection to form.
THE WITNESS: There is no high-quality literature or data that suggests that that phenomena occurs with the TVT device when

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used for the indication of stress incontinence.
The long-term registry trials, which have followed out to ten years, as well as the additional data out to 17 years, do not raise any concern, clinically, that those -- that that phenomena exists.
Now, I have reviewed the information provided by your experts, in which they were to hypothesize that. That information is Level 5 evidence.
Now, let me just show you that.
BY MS. THOMPSON:
Q. I don't need you to show me.
A. No, no --
Q. I didn't ask --
A. -- I do.
Q. -- any question about the level of evidence.
A. But I have to explain to

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you --
Q. Mr. Snell can ask you that question, if you he wants to, at the end.
A. So when you have Level 1 --
Q. I have not asked you that question.
A. Please allow me to finish my answer, counselor.
When you have -- because this is -- this is paramount to my methodology.
When you have Level 1 data, Level 5 data doesn't count, okay?
Additionally, you can never derive clinical implications or draw clinical conclusions from Level 5 data. That is implicit in the weak design of that study. Every author of those papers makes that disclosure, as far as the -- as far as the ramifications.
In fact, I will point to Clave, which I cited in my --
MS. THOMPSON: This is really all nonresponsive. So

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if --
MR. SNELL: No, you asked him do you know of literature. And he's telling you about literature.
THE WITNESS: Yes.
MR. SNELL: And he's saying --
MS. THOMPSON: I'm asked him about literature about immune response to foreign body.
MR. SNELL: He's telling you. He saw what your experts have pointed to --
MS. COPE: Should I start talking, too? You seem to speak freely for him.
MR. SNELL: I'm not speaking for him. You asked me a question, Margaret, I'm going to give you an answer. Don't ask me a question, then.
MS. THOMPSON: Okay. I'm going to request more time if he

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is going to continue to not answer my question.
THE WITNESS: Counselor, I am --
MS. THOMPSON: We'll go off the record, and he can look up his literature that he wants to talk about.
VIDEO TECHNICIAN: We are off the record. The time is 5:15 p.m.
- - -
(Whereupon, a discussion off the record occurred.)
- - -
VIDEO TECHNICIAN: We are back on the video record.
THE WITNESS: The literature that we are discussing here is not applicable to TVT, okay?
BY MS. THOMPSON:
Q. Okay. All right.
A. And it does not have sufficient weight or evidence that you

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can draw those conclusions.
Q. Is your opinion that Level 5 evidence regarding safety issues is also worthless?
MR. SNELL: Form. Objection.
THE WITNESS: When you have Level 1 evidence on safety, then the Level 5 evidence is not considered to be important.
BY MS. THOMPSON:
Q. Do you believe that we have Level 1 evidence on the safety of the TVT --
A. Absolutely.
Q. -- yes or no?
A. Absolutely.
Q. Okay. There's an article, Wang, I believe it's on your reliance list.
A. Yes.
Q. Do you believe that's not a quality study?
A. That is an extremely

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poor-quality study.
Q. And is there evidence to the contrary, that there is no immune -- significant immune response to the polypropylene mesh in the TVT that you are aware of?
A. Can I speak to --
MR. SNELL: Object to form.
THE WITNESS: Can I speak to the Wang study, please?
BY MS. THOMPSON:
Q. No, I -- just answer my question, please.
And the question is, is there--
A. Hold on. I'm sorry, I'm going to ask you to pause.
You did ask me about the Wang study, I want to make sure --
Q. I asked you if you were aware of it. I have not asked you any questions about the Wang study, other than, are you aware of it?
MR. SNELL: Actually, no.

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You --
THE WITNESS: You asked me about the quality of the evidence. I'm going to tell you the answer, and I'm going to tell you what I'm basing my answer on.
BY MS. THOMPSON:
Q. I asked you -- I'm asking you about the evidence that shows that there is no immune response to the foreign body. That's what I would like for you to answer, the question, and tell me if you have evidence that there is no immune response to the foreign material in the TVT.
A. The long-term safety studies -- excuse me. The long-term Level 1 evidence studies speak to the lack of a significant immune response.
In addition --
Q. Okay. Can you --
A. In addition --
MR. SNELL: Don't stop him.
THE WITNESS: -- the

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systematic reviews speak to the fact, and this includes -- and this is consistent with what is stated by the FDA, what is stated by NICE, what is stated by AUA, AUGS, and SUFU, that there is -- that polypropylene mesh, macroporous, as used with the TVT device for its intended purpose, is the most biomechanic -- biocompatible material.

By definition, biocompatible speaks to host tolerance and the lack of immunologic response.

BY MS. THOMPSON:

Q. Can you show me, in any of those things that you just rattled off, where it states that there is no immunologic response to polypropylene mesh in the TVT device?

MR. SNELL: Objection to form.

BY MS. THOMPSON:

Q. I'm looking for immunologic

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response, which is what rejection or graft versus -- versus host versus graft response is.

MR. SNELL: Objection to form.

THE WITNESS: Can we go off record?

MS. THOMPSON: Off the record, please.

VIDEO TECHNICIAN: We are off the record. The time is 5:19 p.m.

- - -

(Whereupon, a discussion off the record occurred.)

- - -

VIDEO TECHNICIAN: We are back on the video record.

THE WITNESS: Yes. Again, I am -- I am trying to be extremely respectful of everybody's time, and acknowledge that this is Friday.

Unfortunately, the volume of

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material as relates to the TVT device, which has been in development over 20 years, is broad and extensive and worldwide. And, you know, unfortunately, there is a lot of material.

And while I'm well versed in it, it still takes me a while to figure out exactly the location of the statements that I have in mind.

Why don't you go back off the record?

MS. THOMPSON: I should be the one who directs the videographer, if you don't mind.

THE WITNESS: I'm sorry. I'm just trying -- I'm just trying to be respectful of people's time, and I'm apologizing for the amount of time it's taking. I'm just -- I want you to know I'm not doing this to be obstructive.

BY MS. THOMPSON:

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Q. And, I mean, we can just concede that you have not been able to find anything on that particular issue in the time allotted.

A. If I can -- if I cannot produce this within the next several minutes, I'm happy to move on, again, out of respect for everybody's time.

Why don't you go ahead and ask me the question, counselor?

Q. The next question?

A. No.

Q. The previous question that we've been -- are we on the record?

MS. THOMPSON: Are we on the record, Greg?

VIDEO TECHNICIAN: We're on the record.

THE WITNESS: I'm sorry.

BY MS. THOMPSON:

Q. Are you ready to move to the next question?

A. Yes.

Q. Hopefully, we won't spend as

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much time on the other things that you've said you've not seen one single patient out of your 3,000 that have had these particular conditions, you said that you have yet to observe a single case of chronic foreign body reaction.

How did you determine that you have not had a single patient, out of 3,000, that has had a chronic foreign body reaction to mesh?

A. So clinical suspicions that one might be experiencing a reaction that would be classified as a chronic foreign body reaction would be things like chronic nonhealing of a wound, persistent erythema, fluctuance, pain, chronic drainage.

Q. But you would agree with me that chronic foreign body reaction is a histologic diagnosis, would you not?

MR. SNELL: Form. Objection.

THE WITNESS: I would say that it is -- it is something that

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always has a clinical presentation and then would be confirmed on it.

Now, in contrast, we have seen this with other implanted material. So I am very familiar with the presentation. In fact, I've published on the presentations within the pelvic floor, in the vaginal space, as it relates to what we referred to, at the time, was chronic granulomatous response to a foreign body within the context of reconstructive pelvic surgery.

BY MS. THOMPSON:

Q. I don't think you answered my question.

Foreign body reaction is a histologic pathologic diagnosis, correct?

MR. SNELL: Asked and answered.

MS. THOMPSON: If you got the answer, I sure didn't.

THE WITNESS: It is both.

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It is both.

MR. SNELL: Would you read it --

THE WITNESS: It is clinical --

MR. SNELL: Would you read it back?

MS. THOMPSON: No.

MR. SNELL: Go ahead and -- go ahead and answer it again.

BY MS. THOMPSON:

Q. Okay. All right. So of these 3,000 patients that you've never seen a chronic foreign body reaction, are you aware that there's literature that states that 100 percent of women with pelvic mesh in their bodies have a chronic foreign body reaction?

MR. SNELL: Objection.

BY MS. THOMPSON:

Q. 100 percent?

Are you aware of that literature?

MR. SNELL: Objection. Form

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and foundation.

THE WITNESS: Rephrase your question, please.

BY MS. THOMPSON:

Q. Are you aware -- are you aware of literature that states that 100 percent of women with pelvic mesh have a chronic foreign body reaction to the mesh?

MR. SNELL: Same objection to form and foundation.

THE WITNESS: If you have a foreign body implanted in your body, chronically, there will always be histologic evidence of the body's reaction surrounding the mesh or the material.

BY MS. THOMPSON:

Q. So that's really --

A. That -- that is not germane or related clinically, nor can you take inflammation that just randomly produces that kind of in vitro, again, Level 5 evidence, you cannot make clinical

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inference. There's not enough power to that study.
The only way that you could make that is by examining Level 1 evidence and deriving that.
Q. Is there Level 1 evidence that states that there is not a chronic foreign body reaction to mesh; yes or no?
A. There is -- there is a chronic -- excuse me.
There is -- the body does respond, in 100 percent of patients, but there's no negative clinical sequelae.
Q. So your statement that you have not had a single case of chronic foreign body reaction, that's not really what you mean, right?
A. No, clinically based. I'm speaking to clinical medicine, clinical problems.
Q. And you know that for a fact, out of your 3,000 patients?
A. To the best of my knowledge, a patient has never presented to me with

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a chronic or acute medical syndrome in which we could identify, as the source, a chronic inflammatory reaction.
Q. And I think that's a little different from what you stated here --
A. No, counselor.
Q. -- so I appreciate that.
A. No. My -- my -- if I speak to my clinical experience, it's clinical. It's not stuff that I'm doing in a lab. I think that's quite clear.
Q. Is less than Level 1 evidence important if you're reporting a death from a minor procedure like the TVT?
MR. SNELL: Objection to form.
THE WITNESS: Well, I think -- I think you're using -- I think you're using the -- I think that you're using the clinical -- clinical evidence pyramid out of context here.
All deaths are important.

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There is no non-important death. You don't -- you don't need Level 1 evidence to tell you that a death has occurred.
BY MS. THOMPSON:
Q. And that's something that you would want to know, correct?
MR. SNELL: Objection.
BY MS. THOMPSON:
Q. As a doctor and a patient?
MR. SNELL: Objection. Form.
THE WITNESS: If a patient of mine were to die as a result of one of my procedures, I would absolutely want to know about the occurrence of the death and the cause of death.
BY MS. THOMPSON:
Q. I'm talking about published in the literature.
Would you want to know other doctors' patients who have died as a result of a TVT or another mesh

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procedure?
MR. SNELL: Object to form.
THE WITNESS: You know, I think that I would be aware of that, yes.
BY MS. THOMPSON:
Q. That wasn't my question, would you be aware of it.
Is it something that you would want to know and see published?
MR. SNELL: Same objection.
THE WITNESS: I don't necessarily think it needs to be published. If someone dies at the hospital next to me, I'm not going to wait until it's published before I think about what had occurred.
BY MS. THOMPSON:
Q. Well, what if a patient dies in Atlanta, Georgia, which happened a little while ago, is that something that you would want to know about?
MR. SNELL: Objection.

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Form. Vague. Lacks foundation.
THE WITNESS: I don't --
BY MS. THOMPSON:
Q. From a TVT.
A. I don't know -- I mean, that an isolated case that happened elsewhere -- I mean, would I want to know? I mean, I wouldn't close my ears if someone told me about the problem.
But had I not heard about it, I wouldn't say that a foul was committed.
Q. Do you routinely send the specimens that you remove when you -- of mesh for histologic exam?
A. We do routinely send -- send specimens to the lab for identification.
Q. Have you ever looked at the slides?
A. I have not looked at the slides.
Q. You've never looked at an explanted mesh under the microscope?
A. I have never looked at an

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explanted mesh under the microscope.
Q. So you really don't know what they look like, do you, under the microscope?
A. Yes, I do. They are in all these articles. There are clear photomicrographs on there with accurate pathologic descriptions. That's not what you asked me.
Q. But you disagree with the pathological descriptions in the literature?
A. You and I are talking about different things.
I have already told you that a foreign material in the body, you will see evidence of that response. You have to see evidence. There -- it's a foreign body and there is -- and there is a thing.
But it's not a clinically significant observation.
Q. All right. You agree with me that there are alternatives to

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midurethral slings?
MR. SNELL: Form.
THE WITNESS: In what context? In the treatment of stress urinary incontinence in women?
BY MS. THOMPSON:
Q. In the treatment of stress urinary incontinence?
A. TVT is only one of several procedures that is effective for the treatment of female stress incontinence.
Q. Okay. The Burch procedure would be one of those, correct?
A. That is correct.
Q. And an autologous sling would be one of those, correct?
A. That is correct.
Q. And there are actually nonsurgical treatments for stress urinary incontinence as well, correct?
A. That's correct.
Q. And can we agree that they have equivalent efficacy?

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A. Across the board, efficacy is similar. Again, you do a meta-analysis, you overweight higher-quality data, you'll get -- you'll get recommendations that say, I favor one or the other.
But I think it's a reasonable statement, as presented in the short-term, that the effectiveness, in the short-term across the procedures are -- demonstrate similar efficacy.
Q. Do you know Mickey Curran?
A. Yes.
Q. I believe you've published with him on one of your papers; is that correct?
A. I've published with Mickey on several papers, correct.
Q. I want to read you and statement and I want you to tell me whether you agree with it or not, okay?
A. May I ask who is making the statement?
Q. Well, Dr. Curran is making

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the statement.
A. Thank you. I just want to make sure it wasn't me making the statement.
Q. But it wouldn't matter, I guess, for the purpose of whether you agree with it or not.
In our opinion, the autologous pubovaginal sling is appropriate for patients with stress urinary incontinence who declined to have synthetic material implanted because of concerns related to long-term placement of synthetic mesh.
Would you agree with that statement?
MR. SNELL: Objection to the form.
Go ahead.
THE WITNESS: Can you tell me the year that that was published?
MS. THOMPSON: 2012, I believe.

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THE WITNESS: I think that's a relatively reasonable statement.
BY MS. THOMPSON:
Q. Reasonable?
A. Yes.
Q. Okay. Thank you. I'll just check on that date for you real quick.
2012.
A. Okay. Thank you.
Q. How much are you paid for placing a TVT on average?
A. The reimbursement for the TVT -- there is no -- there is no specific procedure of TVT. So it's a pubovaginal sling procedure.
So if I place an autologous fascial sling or if I do a synthetic midurethral sling, the reimbursement is about the same. You know, Medicare data, with geographic area factors factored in, in this region, I would say probably the range is $800 to, maybe, $1,200 a procedure.
Q. And how much would you be

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paid for a Burch?
A. I would suspect that the reimbursement for the Burch is likely to be a little bit higher.
But I do want to -- I do want to clarify something. And I suspect that with your background, you would understand what I'm about to say.
We're not paid for the procedure. The reimbursement for, say, the surgery encompasses all services that we provide, 24 hours prior to the procedure for the actual procedure, whatever amount of postoperative care is deemed necessary and pretty much all care out to about 90 days.
So the percentage of what I just mentioned that's specific for placing the procedure, it's probably half that, if you're looking for that specific of information.
Q. And how long did it take you to place a TVT?
A. In my hands, a TVT can be

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placed in about 20 minutes.
Q. And how about an autologous sling -- well, let me ask you this first: Are you performing any autologous sling procedures?
A. In our practice, we don't currently perform autologous fascial slings in the last several years, because we reserve those for a certain subset of patients. And, fortunately, we've not had to go that far down the algorithm.
Q. So it's been several years since you've placed an autologous -- or since you've performed an autologous --
A. That's correct.
Q. -- sling procedure?
How about the last time you were -- performed a Burch procedure.
A. The last time I performed a Burch procedure might be 2002.
Q. But you were trained on both of those procedures, correct?
A. Of course.
Q. Do you teach residents and

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fellows?
A. I do. I don't teach fellows, excuse me.
Q. You teach residents?
A. Correct.
Q. At Thomas Jefferson?
A. No. Lankenau Medical Center has an independent residency.
Q. And I presume, since you're not performing a Burch or autologous sling, you're probably not teaching those to the residents currently?
A. To be honest with you, excuse me, I'm sorry. I may have misspoke, as far as the last time I performed a Burch.
When we're having this conversation, I'm thinking of standalone procedures. There may be combination procedures that we're doing it.
I'll be very honest with you, I don't train -- the residents come to me for, really, basic training. We don't really train them to go on and

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independently perform a procedure like an autologous fascial sling or a Burch. They -- their role, in that kind of a setting, would be more observation or assistance.
Q. Thanks. I know we talked a lot about studies, and I have a few questions that I want to ask you that I think will be relatively simple.
And I know, from talking with you today, that you feel like clinical studies are important, correct?
A. I think that levels of evidence are important.
Q. And you've actually performed and published, including some randomized control trials, correct?
A. That's correct.
Q. And they're -- you would agree with me that they are important so that doctors can make responsible treatment decisions, right?
A. I think that, again, the levels of evidence provided by clinical

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studies are important, yes, in how we practice medicine and how we -- how we make clinical decisions.
Q. And it's important for patients so that they can give informed consent, correct?
A. Yes.
Q. Some noncontroversial questions.
And when you're looking at clinical studies, you want to see safety, correct?
A. It depends upon the context of the study.
Q. But in general, as a -- you know, broadly speaking you want to know the product is effective, correct?
A. You know, again, within the context of that part of medicine that I practice as it pertains to surgery, we would phrase it, it's the balance between risk and benefit.
Q. Okay. So you want studies --

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A. Surgery -- and safety, of course, would straddle risk and benefit.
Q. I agree. And that's fine.
A. And it's relative.
Q. And I'm -- I'm happy to talk about to it -- talk it in terms of risk or complications and benefit or --
A. Yes.
Q. -- treatment success.
And when you're looking at a study, regardless of the level, you want it to provide accurate information, correct?
A. I'm not sure I understand what you're implying by the term "accurate."
Q. You want the data that's presented to be correct? You want it to be -- what the study actually found is what you want to read when you're reading the publication, correct?
MR. SNELL: Form.
THE WITNESS: And I apologize, you know, I am an

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editor within this sphere, so --
BY MS. THOMPSON:
Q. So you're an editor of IUJ?
A. Correct.
Q. And also Female Pelvic Medicine; is that correct?
A. And Reconstructive Surgery, it's one journal.
Q. I just didn't want to say the whole thing, I'm getting tired.
A. It took several decades to come up with that, so I do appreciate if you do say it.
Q. Okay, I will --
A. You can say FMPRS.
Q. I will from now on.
A. Thank you. I worked very hard for that, as you can imagine.
Q. When did you last review an article or IUJ?
A. It's within the last few weeks.
Q. Was that a mesh article?
A. The one in the last couple

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of weeks, I do not -- I know I've reviewed some mesh related articles within the past month, but the one in the last couple of weeks -- sometimes there's mesh involved, but that's not the primary objection, so --
Q. Well, you would agree with me, as an editor --
A. Excuse me. I'm sorry. I would say within the last three weeks, yes, I have reviewed an article primarily on mesh related procedures in this sphere.
Q. And what was -- what was the gist of that article, if you can divulge it?
A. So as you're well aware, the International Journal is an international journal, and so many of the submissions come from other countries. Many of the ones that I look at come either from the Middle East or China or one of the southeast, you know, Asian companies. Oftentimes we get

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manuscripts that relate to a particular center or individual's experience with a procedure. Oftentimes it's some variant of a procedure. And so, typically, it's looking at -- it's looking at that.
Q. And you can't give -- be any more --
A. Anti-incontinence procedure that involved some kind of mesh related material.
And, again, I'm not giving you the name because it doesn't really have a name, it's something that they came up with themselves as an alternative.
Q. Okay. And you want the studies that you look at to be objective, right?
A. You and I can spend hours talking about whether anything is ever objective in this sphere. What we hope is that the studies are well defined, such that biases are apparent and that you minimize the unrecognized biases.

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So, yes, we look at that.
Q. So as objective as it can be under the constraints that it might have?
A. And what goes along with that is that the -- that the endpoints, for example, are objective. You know, that these are not studies, say, for example, somebody picked up a telephone four years or five years later, called up patients and asked them a series of simple questions and then determined that -- determined the rate of success or not success based on that.
You would prefer to have objective data.
Q. Okay. So objective data, to the extent possible, you want to minimize bias or disclose bias, if it exists, correct?
A. Correct.
Q. And you shouldn't decide what the results are going to be before you get the results, correct?
A. You shouldn't, but that's

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often the case.
Q. Would that cause you some concern if you reviewed a study, as an editor of one of those journals, that the results were predetermined?
A. I think that's a different --
MR. SNELL: Form.
THE WITNESS: I'm sorry. I think that's different than what I just interpreted. I don't think -- no, I don't agree -- I don't agree that results are predetermined in the stuff that we look at. I think that there's always, you know -- there's always a bias of what the results mean or what -- you know, what the results mean. So, yes, I mean, my -- my job, as an editor, is to read a study and to determine, did the study have a primary objective, did -- was the design sufficient

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that they could comment on that objective; and, more importantly, when looking at the results, do they accurately interpret the significance of those results.
BY MS. THOMPSON:
Q. What would you do if you were an editor and received a paper where the results were predetermined?
MR. SNELL: Form. Incomplete --
THE WITNESS: I don't know -- I don't understand --
MR. SNELL: -- hypothetical.
MS. THOMPSON: Sorry?
THE WITNESS: -- how I would know they were predetermined.
MR. SNELL: Incomplete hypothetical.
MS. THOMPSON: I'm going to give you -- --
THE WITNESS: If the results are predetermined, you wouldn't need a study.

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- - -
(Whereupon, Exhibit Toglia-7, Bates ETH.MESH 05225354, 05225380-384; TVT Instructions for Use, was marked for identification.)
- - -
BY MS. THOMPSON:
Q. Dr. Toglia, have you seen this document from Ethicon before?
MR. SNELL: I'm going to object. This is part of a larger document that has been provided. You're just cutting two pages.
MS. THOMPSON: And we can get the larger document, if you want him to have it for this purpose.
MR. SNELL: I'm sure it's here somewhere in the files.
MS. THOMPSON: Okay. If you want him to see it, you're welcome to pull it out.
THE WITNESS: Again, I mean,

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I'm not -- I don't know -- understand the context of what this is describing. I'm familiar with the --
BY MS. THOMPSON:
Q. Well, let me ask you this: Dr. Toglia --
A. Yes.
Q. -- did you see the contract with -- between Ethicon and Drs. Olmstead and Nielsen?
MR. SNELL: Hold on. Objection. Foundation and form. And that actually misstates the evidence. Go ahead.
THE WITNESS: I believe that that's outside the sphere of the task that I was given to look at the design and the safety of the TVT device.
BY MS. THOMPSON:
Q. I believe Dr. -- Mr. Snell said that you had this -- the contract

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that this is the attachment to.
A. I'm not -- I'm not telling you that I'm not familiar with this document or that I may not have perused this document.
However, I may not have -- I may not have committed to memory, you know, the details of these things.
I mean, I've looked at thousands of things.
Q. Let's read through it.
A. But for intents and purposes, you know, I would not say that I could speak to the details of what you presented to me.
Q. So you're not giving opinions as to the Olmstead studies regarding TVT?
MR. SNELL: Actually, objection.
THE WITNESS: I think I've given opinions within my expert reports. I'd be happy to pause and point them out to you, if

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you'd like, counselor.
BY MS. THOMPSON:
Q. I guess I just misunderstood your answer.
A. Yes.
Q. Let me -- let me just -- so this exhibit states, The results of the clinical trials will be considered acceptable if, first, they do not differ significantly from the results published in the original article.
To you, is that an appropriate study design?
MR. SNELL: Objection. Misstates. Form.
THE WITNESS: This doesn't refer to that, counselor. This is not -- I mean, this is not saying that it's acceptable to -- for publication, that -- this doesn't -- I mean, the fact that it speaks to the results has nothing to do with the design.
I -- may I give you my

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interpretation of what we're looking at here?
BY MS. THOMPSON:
Q. No, you don't need to give me your interpretation. I'll ask you --
A. You've asked me about this document.
Q. -- you a question and you can answer it.
So if the investigators were only paid if these objectives were met, would that be an appropriate design for a clinical study?
MR. SNELL: Objection to form.
MS. THOMPSON: That's a hypothetical.
THE WITNESS: Yes, I understand. My -- let's make sure we're talking about the same studies.
My understanding is that this is referring to the multicenter studies on the TVT

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device and that Olmstead did not -- was not a participating site in the multicenter study. But Olmstead was the individual becoming -- who was being paid.
Am I correct?
BY MS. THOMPSON:
Q. Who told you that? Or where did you come up with that?
A. Nobody told me that. That was just -- I'm just asking you, that was kind of my -- that's kind of where I'm coming from.
Can you show me the specific study that we're referring to here?
Q. Mr. Snell -- I'm just asking you about this contract.
A. I'm asking you whether you can show me -- I don't know what this is connected to, what study this is connected to.
Q. There have been multiple studies that have been published --
A. Right.

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Q. -- from the original cohort --
A. Right.
Q. -- correct?
MR. SNELL: Objection. Form. Vague.
THE WITNESS: I will answer that question.
The original -- I don't know -- the original Olmstead study involved, I think, roughly about 50 patients. I don't -- I'm aware of the longitudinal studies where Nielsen published on the same cohort of patients at a year, two years, five years, seven years, you know, ten years, et cetera, twelve years, et cetera, et cetera, so on, 11.5 years, 17 years.
That's not -- I'm just clarifying. That's not the same as Olmstead. Olmstead's original report was a series of, I think,

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roughly 50 patients that he himself operated on.
And I don't believe that this document refers back to that original study.
BY MS. THOMPSON:
Q. Is this -- is it an appropriate study design where the investigator is paid if certain criteria are met when the results are published?
MR. SNELL: Objection to form. Misstates the evidence.
THE WITNESS: I don't --
MR. SNELL: Asked and answered.
THE WITNESS: I don't know how to answer that. I'm sorry.
BY MS. THOMPSON:
Q. So you don't know how to answer a question about you're only going to get paid if you get these results?
MR. SNELL: Hold on. Objection. Argumentative.
MS. THOMPSON: I'm just

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trying to understand his answer.
THE WITNESS: No, no, I understand.
And, counselor, I understand that you are -- here is my problem and my confusion, okay? You are, at the same time, asking me a very general question about things I do as an editor in science in general.
At the same time, you're putting a very specific document, in isolation, and not providing me with the reference study and you're asking me to make a comment in the middle that seems to link one with the other.
And I'm telling you, I'm not able to -- I don't know how -- not that I'm -- not that I'm will -- I'm not willing to, I don't know how to make an answer about a study that I don't know -- don't know anything about.

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BY MS. THOMPSON:
Q. I'm only talking about the design of a study.
Is this an appropriate design of a study?
MR. SNELL: Objection to form.
THE WITNESS: This paper does not address a design of the study. This paper does not stipulate if the study is not designed to our satisfaction, they'll be no reimbursement. This study speaks to results.
BY MS. THOMPSON:
Q. Okay. We'll move on.
A. And the results have nothing to do with the design. Nor do I see a phrase that says, the study has to be designed such that these results must be --
Q. No. It's just the investigator wasn't paid if the results weren't -- weren't met.

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MR. SNELL: Objection. Move to strike.
BY MS. THOMPSON:
Q. Were you shown -- prior to working in this lawsuit, were you shown the material safety data sheet related to the polypropylene used in Ethicon mesh devices? And you're a chemist, you know what a material safety data sheet is --
A. I do.
Q. -- correct?
A. I do.
No. I did not -- I did not previously look at that material.
- - -
(Whereupon, Exhibit Toglia-8, ETH.MESH 08696131-132, Exhibit C - Clinical Trials, was marked for identification.)
- - -
THE WITNESS: We're talking specifically about regulatory paperwork. This is non-clinical regulatory type stuff.

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MS. THOMPSON: I don't think there was a question pending, but I don't think -- sorry. I don't think the material safety data sheet is a regulatory document.
BY MS. THOMPSON:
Q. Okay. Have you seen the material safety data sheet now, since you've been working on this lawsuit?
A. Yes. This was part of the -- this was part of the materials provided to me.
Q. And I'll direct your attention to Number 10 in the material safety data sheet regarding stability and reactivity.
A. Yes.
Q. Could you read the sentences under incompatibility?
A. The following materials are incompatible with this product. Strong oxidizers, such as chlorine, peroxides, chromates, nitric acid, perchlorates, concentrated oxygen, sodium hypochlorite,

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calcium hypochlorite, permanganates, chlorine and nitric acid.
Q. And are those compounds found in the human body?
A. Within the context of this type of testing, I would say they are probably not. And I don't see -- I don't see anything that says that -- that references in concentrations normally found within human tissue.
Q. And under Number 15, other information --
A. Yes.
Q. -- component toxicity, could you read the sentences after that?
A. Sure. Polypropylene has been tested in laboratory rats by subcutaneous implants of disc or powder. Local sarcomas were induced at the site of implantation. No epidemiologic studies or case reports suggest any serious chronic health hazards from long-term exposure to polypropylene decomposition products below the

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irritation level.
Q. Did Ethicon perform any studies to determine whether or not the polypropylene used in their mesh devices causes sarcoma in humans?
A. I don't see that -- that discs of polypropylene or powders of polypropylene have anything to do with the TVT device when used for its proper indication of stress incontinence in women.
I think that the science in this area, it is well known that the formation of sarcoma is related to form, form material, and that you can't extrapolate from laboratory rats to humans.
Q. So the answer is you're not aware of any studies that Ethicon did to determine whether a TVT mesh could lead to sarcoma?
A. Let me just refer to my report for a second.
I think it's fair to say

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that they did not, but I don't see -- I wouldn't understand why that would be -- why that would be relevant.
Q. Is this information something you would want to know, as a physician?
MR. SNELL: Objection to form.
THE WITNESS: Maybe if I was a veterinarian caring for rats and I was implanting discs or powders.
But this information is not pertinent or clinically relevant.
BY MS. THOMPSON:
Q. Is this information about the polypropylene used in the Ethicon pelvic mesh products something that patients should be informed of?
MR. SNELL: Same objection.
THE WITNESS: To the best of my knowledge, polypropylene discs or powders are not used in the TVT product. And at the same time, the TVT product is not used in

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rats.
BY MS. THOMPSON:
Q. But the fact that the disc and powder in rats may cause cancer is irrelevant, in your opinion?
A. I think animal studies have established that -- that it's related to both the -- the animal and the form and that it is not transferable to humans.
Q. Are you familiar with the term "latency period"?
A. Yes.
Q. Do you know what the latency period for exposure and development of sarcoma is thought to be in humans?
A. No, I'm not.
Q. Would it surprise you if it's 30 years?
MR. SNELL: Form. Vague. Lacks foundation.
THE WITNESS: It probably would surprise me, yes.
BY MS. THOMPSON:
Q. Has a TVT been implanted in

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a human for 30 years?
A. If the first clinical trials of a TVT were published somewhere around '96, we would be 20 years. Did I do that wrong? I was thinking '86.
We are probably a few -- we're probably a few years shy of that.
Q. All right. I'm going to ask you about whether or not you had seen any documents or whether Ethicon had told you about certain things prior to your involvement in this lawsuit, okay?
A. Okay.
Q. Is that -- do you understand?
MR. SNELL: Can I say one thing? Off the record.
VIDEO TECHNICIAN: We are off the record. The time is 6:04 p.m.
- - -
(Whereupon, a brief recess was taken.)
- - -

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VIDEO TECHNICIAN: This marks the beginning of Video Number 4. We are back on the record. The time is 6:06 p.m.
BY MS. THOMPSON:
Q. So, Dr. Toglia, I'm going to ask you some questions about whether you either saw documents or Ethicon told you about certain things. And this would all be prior to your involvement in this lawsuit.
A. Yes.
Q. Did Ethicon tell you that mechanically cut mesh thins or stretches when it's placed under tension?
MR. SNELL: Form.
THE WITNESS: I don't need Ethicon to tell me about the properties of the material, given that I handle it on a frequent basis.
BY MS. THOMPSON:
Q. And other doctors don't need that information either?

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A. I'm sorry, I don't see the relationship to that -- the question.
Q. Is it your opinion that doctors generally don't need the information that Ethicon has about the mechanically cut mesh thinning --
A. All right.
Q. -- and stretching on tension?
A. So we're no longer talking about what you said that we're going to talk about, which was Ethicon's communication with me on this material? Are we done with that?
Q. Well, on this particular item, I want to know whether you think -- you said it's not -- you don't need to hear it from Ethicon.
A. Correct.
Q. I'm asking you, do other doctors need to hear it or would want to hear it from Ethicon?
MR. SNELL: Form.
THE WITNESS: I don't

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know -- I don't know what other doctors would need or want to hear. I think that, you know, in the -- prior to my involvement in this matter, there were discussions amongst physicians and Ethicon engineers, and other people, where we discussed the properties of mechanically cut mesh and how it behaves under both physiologic and nonphysiologic, you know, circumstances.
I would say, again, as a surgeon, the nonphysiologic stuff really is of no clinical meaning, nor do I think that you can infer any kind of clinical importance to that information.
BY MS. THOMPSON:
Q. Okay. And even if Ethicon thought it was clinically important, you didn't feel like you needed to have that information?
MR. SNELL: Form.

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THE WITNESS: Again, I don't rely upon Ethicon to tell -- to provide me with information as it relates to how I manage patients or the materials that I use.
BY MS. THOMPSON:
Q. And you're not -- you do not feel like you can give an opinion as to whether other doctors would want to or need that information?
A. I think that's beyond the scope of what I've prepared, yes.
Q. Okay. Did Ethicon, and there are going to be a whole bunch of these, so if your answer is the same we can kind of go with that.
A. I don't know what you're going to ask me.
Q. Did Ethicon tell you or show you documents showing fraying of mechanically cut mesh?
MR. SNELL: Form.
Go ahead.
THE WITNESS: I've seen

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documents that -- I don't know that I would use the word "fraying," per se. I think you're implying, you know -- or labeling, per se.
BY MS. THOMPSON:
Q. You've never seen documents that use the word "fraying"?
A. No, there are documents that use the word "fraying."
Q. Ethicon documents?
A. There are Ethicon documents that use the word "fraying." I have seen those documents.
Q. So, at least, people at Ethicon called it fraying?
A. Yeah. I just -- I just -- what's the working definition of fraying? Is your definition of fraying the same as mine? The same as theirs?
Q. But is that the same, in your opinion, that that -- that information is irrelevant to you in your practice?

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A. No. I don't think that's what I'm speaking to. Information is relevant. Whether it's relevant that Ethicon absolutely had to communicate one-on-one with me on that particular issue is what I'm speaking about.
Q. I don't -- I don't think I asked about one-on-one.
I'm just asking you, is that information that you would have liked to have known, if Ethicon had that information?
A. I did know about that information, and I did receive that information from Ethicon.
Q. Okay. And did other doctors receive that information --
A. Yes.
Q. -- that mechanically cut mesh frayed?
A. Yes.
Q. Did you teach about that when you were doing your courses or doing your preceptor training?

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A. Well, again, the fraying occurred at nonphysiologic, you know, forces. And so, yes, I think that we did talk about mesh, its properties, its behavior, how the -- how -- why it was important to adhere to the well-described steps of the procedure in order for the mesh to perform with -- under the normal physiologic load, under the normal physiologic capacity, and in that capacity, fraying was not a clinical concern.
Q. Who told you that these were nonphysiologic forces?
A. Based upon, you know, my body of knowledge, reading the material, discussing with other experts, you know, having to do a little bit of reading about physiologic forces.
I mean, physiologic forces within the pelvic floor, obviously, is somewhat unique to our subspecialty. I don't expect that people are taught that in medical school, for example.

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Q. So if Ethicon thought -- Ethicon thought they were using physiologically forces, you would disagree with them?
A. I'm sorry?
Q. If Ethicon, when they did their testing, stated that they were using physiologic circumstances, you would disagree with them?
MR. SNELL: Objection to form. Vague.
THE WITNESS: I would disagree that they were using phys --
BY MS. THOMPSON:
Q. The amount of stretch, for example? The tension applied, for example?
A. I mean, the only --
MR. SNELL: Same objection.
THE WITNESS: I can answer it like this: I am aware that Ethicon conducted testing looking at the mechanical properties of

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the mesh and that that testing started from no -- you know, no tension through the physiologic range to supraphysiologic range.
It was looked -- it was looked upon -- and this is all kind of -- how the material behaves in that regard, to be honest with you, has very little to do with how the material behaves once it's incorporated or placed within the body.
But I know that -- I know that they did perform those tests. I've seen the results of those tests. We have probably, in the past, spoken about data that talks about the different meshes, are they similar -- are they different, similar, physiologic load, supraphysiologic load. Those were all fairly freely discussed.
BY MS. THOMPSON:

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Q. What about roping or curling of the TVT mesh, was that something that was discussed with you prior to your involvement in this lawsuit?
A. Well, I can -- again, I can tell you, from using that mechanically -- mesh for an extended period of time, you know, the mesh does not rope or curl when it's -- when -- you know, in the context that it has a -- the protective sheath over it. And we don't place the mesh without the protective sheath.
When the meth -- so when you're delivering the mesh in the TVT procedure, the sheath is carrying the mesh. The mesh is passive. The mesh is not exposed to the those forces. It's only after the sheath is positioned that you pull the mesh off. Somewhat like the magic trick where you kind of -- not that it's a magic trick, where you pull the table cloth and the stack of cups goes undisturbed.
The mesh is never, in the

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clinical application of the TVT, as we use it, as I use it for stress incontinence, we don't apply any physiologic force.
The only -- the only thing that I would say is that you've got minimal static and rolling friction that does occur as you remove the sheath and the mesh is left behind.
Q. So your -- your testimony is that the mesh, if it is placed flat, remains flat?
A. Correct.
Q. And if Ethicon had evidence to the contrary, is that something that you would like to know about?
MR. SNELL: Form.
Go ahead.
THE WITNESS: It wouldn't hurt my feelings if I was not aware of that information. I don't see how that information is clinically relevant in my world.
BY MS. THOMPSON:

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Q. And would that be the same for other physicians as well?
A. I can't speak to what other physicians might consider to be relevant.
Q. If Ethicon had information that the fraying, roping and curling actually increased the risk of retention, is that information that you would like to have?
A. I -- I would --
MR. SNELL: Form. Foundation.
THE WITNESS: -- say that I know that information independent of that -- I don't need that information -- okay, Ethicon does not implant these meshes in women. I implant these meshes in women. I implant these meshes in over 100 women a year for the past 17 years. I am well aware of how this particular material behaves within the body, and I can tell you, when it is done properly,

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there is no roping, there is no curling.
BY MS. THOMPSON:
Q. And is that information that other physicians would -- would want to know or need to know from Ethicon?
MR. SNELL: Form.
THE WITNESS: I would say within the context of the instructions for use, which outlined, in great detail, the very specific steps that are to be taken, when performed in that manner, there is no roping or curling of the material.
And keep in mind, we're talking about the tension-free placement of the mesh. So that excludes --
BY MS. THOMPSON:
Q. And you'll agree --
A. So that excludes all of the testing that you are referring to, because all those testing refer to

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tension, whether it's physiologic or nonphysiologic.
Q. You'll agree with me that the mesh shrinks, contracts?
MR. SNELL: Form. Overbroad.
THE WITNESS: As a general sense, a hernia mesh, there is shrinkage. Whether there is shrinkage in a TVT mesh, I don't believe that there is clinically significant shrinkage.
Now, of course, because this is the most highly biocompatible mesh there is, it allows for the ingrowth of fibroblasts and reticulocytes. It allows for the infiltration of white cells and angiogenesis.
As the tissue heals against the mesh, the mesh is going to change, and that is expected. And that was actually the -- the original design of the TVT

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specifically spoke to the fact that the mesh would -- the mesh would induce collagen formation and other structural changes in the area around the mesh. And that was considered to be an important part of the clinical effect.
BY MS. THOMPSON:
Q. What's your basis for saying TVT is the most highly biocompatible mesh there is?
A. I'm sorry. Macroporous polypropylene mesh that is classified as Type I by the Amid classification. Of which --
Q. And that's what --
A. -- of which --
Q. -- you believe TVT is?
A. Of which TVT has been the most extensively studied.
Q. And you believe that it is?
A. I know it is, yes.
Q. Despite Ethicon documents

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stating otherwise?
MR. SNELL: Objection to form. Misstates the evidence.
THE WITNESS: My opinion, as an expert, the TVT mesh is Type I, regardless of Ethicon were to tell me yes or no.
BY MS. THOMPSON:
Q. Okay. If Ethicon had information that showed that the fraying, roping and curling causes the pores to collapse or close and render the mesh no longer macroporous, is that information that you would like to know about?
MR. SNELL: Form. Foundation.
THE WITNESS: I don't see how it's relevant, counselor, okay?
BY MS. THOMPSON:
Q. That's -- that's a perfectly acceptable answer.
A. As a surgeon, is it -- is it effective.

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Q. If Ethicon -- and that goes the same for other doctors as well?
A. I can't speak to what other doctors might hold to be important or what they might comment.
Q. If Ethicon has information that fraying, roping and curling of their mesh leads to an increased risk of erosion, is that information that you would like to have?
MR. SNELL: Form. Foundation.
THE WITNESS: I can tell you I have an independent opinion that, yes, if the mesh were to curl, that there might be an increased risk of erosion relative to a mesh that has not curled.
Now, the risk of exposure might go from, say, .6 to .7 percent, which is what it has been in most clinical trials; maybe that might go up to, say, 1.2, 3 percent, 3.2 percent.

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But I would agree -- I mean, I would say I have had the same observation, and I don't need to hear that from Ethicon, that if the mesh is not placed in a tension-free manner -- the mesh is not going to rope or curl if it's tension free. Because in it's native state, the mesh is not roped or curled.

BY MS. THOMPSON:

Q. And I think you've already stated that if it's placed flat, in your opinion, it remains flat?

A. That's correct.

Q. If Ethicon had information that fraying and roping and curling of mechanically cut mesh leads to an increased risk of bridging fibrosis, is that information you would want to have?

MR. SNELL: Form.

THE WITNESS: I would -- again, bridging fibrosis, in my opinion, is likely to be a natural

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or an expected outcome. It's, again, speaking to what the original design -- it was hoped that there would be the induction of collagen, mature collagen formation.

And that, yes, I mean, all of these procedures, in the -- in the world of prolapse incontinence, you're kind of hoping that there's a certain degree, again, within a physiologic range, that there's fibrosis, that occurs, absolutely.

BY MS. THOMPSON:

Q. In other words, replace with scar?

MR. SNELL: Form.

THE WITNESS: I don't know how it is that you're interpreting scar. I'm talking about the -- you want it to induce a certain amount of collagen formation; in a very loose sense scarring, sure.

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All surgical procedures result some scarring.

Now, whether those -- that scarring occurs from the incision that I've made, whether it occurs from the suture that I've placed, whether it occurs based upon something else I may do, I don't know how I would separate, you know, one from the other.

You can -- you will never have no scarring, despite what the TV ads will say. There's no scarless surgery.

BY MS. THOMPSON:

Q. Do you use polypropylene suture in the vagina?

A. Yes.

Q. For what procedure?

A. Again, the vast majority of what I do in the reconstructive world involves some -- some formulation of polypropylene. Polypropylene sutures are commonly used in all of urogynecology for

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apical vaginal suspensions.

Q. When you place a polypropylene suture, how much suture is left in the body? What's the length of suture?

A. I would say that the length of suture left behind, understanding that, obviously, we've tied a series of knots, I don't know if you're -- you just want -- I mean, the whole thing, in aggregate, is less than a centimeter.

If I were to unwind or untie it and stretch it out, that could be, maybe, 3 centimeters. But I don't think that's an accurate -- accurate description. I would say, in general, it's half a centimeter to a centimeter.

Q. And do you have any idea how much -- what the length of suture with filaments would be if you stretched out all the polypropylene in a TVT?

MR. SNELL: Objection to form.

THE WITNESS: I don't have

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any -- but, again, keep in mind, all the procedures I'm describing, if I'm doing autologous fascial sling, I'm using very long polypropylene sutures. If I'm doing a Burch suspension, I am using 4 to 6 polypropylene sutures.

It's the same.

BY MS. THOMPSON:

Q. So it's your opinion that mesh devices like the TVT and sutures are essentially the same?

A. No, that's not what I said. I said the polypropylene material is commonly used in urogynecologic surgery. It is the same -- it is the same material -- it's based upon the same base material whether I'm doing an autologous fascial sling, whether I'm doing a Burch suspension, whether I'm doing an vaginal apical suspension, whether I'm doing a synthetic midurethral sling; understanding that when I say synthetic

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midurethral sling I am specifically referring to the Retropubic TVT device.

Q. Where is the suture placed with an autologous sling?

A. Well, the -- there is an autologous -- excuse me, there is a polypropylene suture typically attached at either end of the sling. It is passed, in a similar manner, through a vaginal incision, up through the space of Retzius, up through the rectus fascia into the subcutaneous space, analogous to a TVT procedure. The difference is, it's tied with tension across itself in that manner.

Q. But there's no polypropylene underneath the urethra when you do an autologous sling procedure, is there?

A. Under the urethra? Well, it's -- unless someone uses a smaller piece of polypropylene to stabilize the mesh under the urethra. And I have seen that.

But I would say, you know,

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the intended procedure, it's the fascia that is below it.

Q. And there's no suture when you are doing a Burch procedure that's placed underneath the urethra, is there?

A. Well, the Burch procedure, as I commented earlier, has nothing to do with the urethra. It's a procedure that stabilizes the bladder neck.

Now, you know, I -- it just occurred to me that, you know, we have used the material of the sling in the field of urogynecology for probably between 30 and 50 years. You know, it's surprising to me that if the latency for sarcoma is 30 years, we should be seeing those patients. In fact, we should be seeing those patients now.

MS. THOMPSON: I don't think there was a question about that, so I'll move to strike that answer as nonresponsive.

BY MS. THOMPSON:

Q. If Ethicon had information

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that the fraying, roping and curling led to a diminished tissue integration, is that information you would want to know?

MR. SNELL: Form. Foundation.

THE WITNESS: Again, I don't rely upon Ethicon to communicate that information. But I have had discussions with them. I'm aware -- they did communicate that information to myself.

BY MS. THOMPSON:

Q. And is that information other doctors should or would want to know?

A. I can't speak to what other doctors should or would want to know.

Q. If Ethicon had information that the fraying, roping and curling of mechanically cut mesh led to an increased risk of infection, is that information you would want to know from Ethicon?

MR. SNELL: Form and foundation.

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THE WITNESS: Again, I would want to know that information from well-designed, high-level studies, especially -- you know, that's where I would seek that information.

I'm sorry, if you're satisfied with that answer, may I take a break to go to the bathroom?

MS. THOMPSON: Let me just -- I have about, like, one more question in this section.

THE WITNESS: May I be a little more insistent that I be --

MS. THOMPSON: Yeah, sure.

THE WITNESS: -- allowed to take a break to go to the bathroom?

MS. THOMPSON: Yes, sir.

VIDEO TECHNICIAN: We are off the record. The time is 6:27 p.m.

- - -

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(Whereupon, a brief recess was taken.)

- - -

VIDEO TECHNICIAN: We are back on the record. The time is 6:40 p.m.

BY MS. THOMPSON:

Q. Dr. Toglia, had you reviewed the instructions for use for the TVT when you started using the device?

A. Yes, absolutely.

Q. And did you periodically review the instructions for use as you were teaching courses and acting as a preceptor for Ethicon?

A. I did, yes.

Q. Do you know whether the instructions for use changed over the time period between 1998 and 2015?

A. Yes. My recollection is that part of the work that I did with them, particularly on the TVT EXACT® product, we re-looked at the instructions for use. Certain points were felt that

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needed a little bit more emphasis or clarity. There was, maybe, a little bit more specificity in some areas, a little less specificity in other areas.

Q. Did the adverse reactions section change at all during that time period?

A. I'm not -- I can't give you an independent recollection of that, as we speak. To me, the instructions for use, I focused on, you know, my -- my focus is actually the instructions on using the device.

Q. But this -- this document would have been provided to physicians at your training courses, correct?

A. I believe so, yes.

Q. In your report, I believe, you stated that, IFU is clear, useful and adequate to describe the procedure and potential risks.

Does that sound right?

MR. SNELL: What page are you on?

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MS. THOMPSON: Page 17, at the top of the page.

MR. SNELL: Thank you.

BY MS. THOMPSON:

Q. The IFU and professional education for the TVT are clear, useful and adequate to describe the procedure and potential risks.

I'm just reading that from your report.

A. I'm sorry, as usual, I'm a little slower than -- than you all.

You're saying it's on Page 15?

Q. I think I said 17.

A. Yes.

Q. And then -- and you go on to say that, Risks of SUI surgery are obvious to surgeons and as surgeons, we are expected to be aware of the risk in light of our education, training and experience.

A. Yes.

Q. Do you believe that a

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company --
MR. SNELL: Let's go off the record.
VIDEO TECHNICIAN: We're off the record at 6:43 p.m.
- - -
(Whereupon, a discussion off the record occurred.)
- - -
VIDEO TECHNICIAN: We are back on the record.
BY MS. THOMPSON:
Q. Do you believe, Dr. Toglia, that a company can assume that doctors know certain risks and avoid warning of the risks as a result? That's a yes-or-no question.
MR. SNELL: Form. He doesn't have to answer yes or no, he can answer how he sees fit.
BY MS. THOMPSON:
Q. Do you want me to repeat it?
A. Well, I know that -- that this is one of -- you know, as a surgeon

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that does anti-incontinence procedure, I'm doing all the other procedures, this is an additional procedure that I'm doing, this procedure is based upon foundation principles that are somewhat common to the other procedures.
And so, naturally, it follows that a risk of, say, bladder injury or a risk of bleeding, the risk of infections -- again, these are -- these are inherent risk and elemental risks of all surgical procedures.
We're not teaching these procedures to non-surgeons to do. It's not that I'm picking a family practice doctor and saying, here, why don't you do this, you've got some patients.
So it's -- I think it's predicated that, you know, a surgeon, you know, that was interested in using a TVT device in lieu of a different procedure that they were presently performing understands the general risks of surgery. I think that's what that statement speaks

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to. That was my intention in making that statement.
Q. So you're -- you're speaking of the general risk of surgery, not those that are specific to the TVT device?
A. I'm talking about the risks that are specific to anti-incontinence procedures in women.
MS. THOMPSON: We can stop there.
THE WITNESS: No, keep going. That's fine. If you like.
MR. SNELL: I'm hungry.
MS. THOMPSON: We'll stop.
VIDEO TECHNICIAN: We are off the record. The time is --
THE WITNESS: That's fine.
VIDEO TECHNICIAN: We are off the record at 6:47.
- - -
(Whereupon, a dinner recess was taken.)
- - -
VIDEO TECHNICIAN: We are

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back on the record. The time is 7:24 p.m.
BY MS. THOMPSON:
Q. Before we get started with the rest of the questions, Dr. Toglia, I've looked through the materials that you've brought.
A. Yes.
Q. And it looks to me like that top cardboard box has the materials that were not the ones related to your report and the materials that Mr. Snell provided you.
MS. THOMPSON: So if we could just mark that box -- the contents of that box as an exhibit for the deposition.
MR. SNELL: I don't know if that's accurate, but you can mark whatever you want to.
MS. THOMPSON: That was what I kind of determined. Everything else looked like it was either depositions or documents or

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literature related to the report. So we'll just do that.
MR. SNELL: Well, I did -- I mean, we sent him the depositions after his report and all the exhibits and stuff.
MS. THOMPSON: Yeah, but I don't need to mark those.
And then did you say that you brought some thumb drives also? I didn't see those.
THE WITNESS: It's essentially this -- this material here.
MS. THOMPSON: It's basically this stuff, too?
THE WITNESS: I can guarantee you it's no different.
MS. THOMPSON: Let's mark these.
THE WITNESS: One of them is simply -- one of them is simply the expert reports.
MS. THOMPSON: So the box

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and the two thumb drives.
- - -
(Whereupon, Exhibit Toglia-9, ETH.MESH 02026591-595, Material Safety Data Sheet, was marked for identification.)
- - -
(Whereupon, Exhibit Toglia-10, Three Thumb drives produced by Marc Toglia, M.D., was marked for identification.)
- - -
BY MS. THOMPSON:
Q. Dr. Toglia, I think before the break, we were just beginning to talk about the instructions for use.
A. Yes.
Q. And I believe you said that you reviewed them throughout the time period and up to the present day that you've been using TVT on a -- on some kind of regular basis or --
A. TVT and TVT EXACT®.
Q. TVT and TVT EXACT®, thank

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you.
Do you believe that the instructions for use are complete?
A. I believe that the instructions for use do exactly that, they -- they accurately describe the instructions on how the product is to be used. They provide the step-by-step mechanics of the procedure.
Q. And complete and accurate in terms of the listing of potential risks as well?
A. I'm not sure what you mean by "complete." I mean, I think it would be impractical to reissue the instruction for use every week or two. Those are provided inside the box.
I don't -- I don't know what form -- you know, what program is used to determine how often to update those.
Q. Do you know if -- I believe I already asked you the question about how often they were updated. But I can't remember the answer.

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A. No, you didn't ask me that question.
To the best of my knowledge, I'm aware of the initial and then the update that occurred roughly around the time the EXACT® was introduced, I believe.
Q. And are you aware of an update that occurred some time this year?
A. I am aware, yes, I did see that. There was an update.
- - -
(Whereupon, Exhibit Toglia-11, Selection of Materials produced by Marc Toglia, M.D., was marked for identification.)
- - -
BY MS. THOMPSON:
Q. I have marked the TVT instructions for use as Exhibit Number 7. And I just have a few questions for you.
A. This is the original?
Q. This, I believe, is from -- from 2000.

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A. Please, do not ask me to read anything from this.
Q. Oh, yeah, I'm sorry about that.
A. Yeah, in Spanish.
Q. Let me read -- sorry this the smallness of that print.
A. I think this is Turkish.
Q. We're not going to read the Turkish.
MR. SNELL: I have 7 marked as the Olmstead clinical thing. And I think you just said this was 7.
MS. THOMPSON: You know what, we had marked this earlier as 7 and then --
MS. COPE: What's the sticker say on it?
MS. THOMPSON: The sticker says -- Dr. Toglia, what does the sticker say?
THE WITNESS: Mine says 7.
MS. THOMPSON: Yeah, we put

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a 7 instead, so let's change it to 8.
- - -
(Whereupon, a discussion off the record occurred.)
- - -
MS. THOMPSON: Off the record till we get our exhibit straight.
VIDEO TECHNICIAN: We are off the record. It's 7:30 p.m.
- - -
(Whereupon, a discussion off the record occurred.)
- - -
VIDEO TECHNICIAN: We are back on the record.
BY MS. THOMPSON:
Q. Dr. Toglia, these were how the instructions for use were produced to us, and I apologize for the small print.
But I'll read you what I want to ask you about, and if you -- if you can tell at least that it's kind of

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close. And we will not be reading the Turkish or Spanish or any other language.
On the --
A. There's Italian.
Q. And Italian. Do you know Italian?
A. No.
Q. On the second page, Bates number 380, under TVT device, it states, This bidirectional elastic property allows adaptation to various stresses encountered in the body.
A. Where do you see that?
Q. Under TVT device, the second paragraph, the last sentence.
A. And, I'm sorry, this is from when?
Q. 2000.
A. Okay. I'll accept that.
Q. The bidirectional elastic property allows adaptation to various stresses encountered in the body.
Do you know what the basis for that statement is?

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MR. SNELL: Objection. Completeness.
Go ahead.
THE WITNESS: I don't know the direct -- what the direct basis is.
BY MS. THOMPSON:
Q. Would you agree that the bidirectional elastic property allows adaptation to various stresses encountered in the body with the TVT device?
A. I would assume that it allows adaptations within two directions, bidirectional.
Q. And is it your understanding that that's what the TVT does, how the TVT behaves?
MR. SNELL: Form.
THE WITNESS: Again, I'm not familiar with the context, so I don't -- can't answer that question, sorry.
BY MS. THOMPSON:

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Q. Did you ever ask Ethicon, during the time that you were serving as a preceptor, what was meant by that statement?
A. I don't believe I ever asked them what was meant by that statement.
Q. On the next page, under instructions for use, the first sentence, The procedure can be carried out under local anesthesia, but it can also be performed using regional or general anesthesia.
Do you perform most of your TVTs under local or general?
A. The majority of our procedures, the vast majority, are performed with -- not with general anesthesia. It's local anesthesia with monitored anesthesia care, which is intravenous sedation.
There are times, of course, the patient may request general anesthesia. There are times that the anesthesiologist might be insistent on

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general anesthesia.
I present it as a procedure that we advocate for local with monitored anesthesia care.
Q. And with the MAC anesthesia, the patient is asleep, although not under a full general anesthesia, correct?
A. As you know, sleep is not a medical term. I would say the patient is not conscious.
Q. If Ethicon had information that the success rate was higher if a local anesthesia was used, is that information that you, as a physician, would like to have?
MR. SNELL: Form. Foundation.
THE WITNESS: I've got to be honest with you, I would not allow Ethicon to -- I mean, I'm the surgeon, I do the procedures, they don't. I don't think the form of anesthesia has any influence.
I think that early on we

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would talk about whether -- how do you -- how do you set the mesh in its final position, whether you use a, quote/unquote, cough test, which, obviously, you couldn't do with general anesthesia, do you simply eyeball it, use a spacer.
I think, really, the underlying message was always that you don't tension -- you don't put tension on the mesh or position the mesh in an obstructive manner.
I don't believe, nor am I aware, that the success rates are higher. I don't believe that there are any high-quality studies that randomize people to one or the other.
BY MS. THOMPSON:
Q. Is that information that other physicians would like to have, do you believe?
A. I know that in the course of training, when I would train a physician,

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it's something that we would discuss, you know, as -- as an option.
Q. Under adverse reactions, Bates Number 3883 --
A. Yes.
Q. -- the IFU states, Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
Is that a correct statement?
A. I would assume if it was included in here, that they believe that that was a correct statement.
I can't tell you that I personally have ever witnessed any of that.
Q. And that's because, of your 3,000 patients with pelvic mesh, you've never observed a foreign body response, correct?
MR. SNELL: Objection. Misstates.

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THE WITNESS: I'm speaking, in this case, specific to the -- to the TVT procedure.

Again, it's at the wound site, so result of the suture material, cautery, how rough you are with the tissue.

I don't -- I don't interpret this as having anything to do with the mesh, per se. I read it literally, which is that there may be local irritation at the wound site and that it is a transient phenomenon.

BY MS. THOMPSON:

Q. Under actions, the IFU states, Animal studies show that implantation of PROLENE® mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent

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tissue. The material is not absorbed nor is it subject to degradation or the weakening by the action of tissue enzymes.

A. I believe that's an accurate statement, yes.

Q. I believe that's all the questions I have on the IFU.

MS. THOMPSON: Off the record for a couple minutes, please.

VIDEO TECHNICIAN: We are off the record. The time is 7:39 p.m.

- - -

(Whereupon, a discussion off the record occurred.)

- - -

VIDEO TECHNICIAN: We are back on the record.

BY MS. THOMPSON:

Q. Dr. Toglia, I'm going to ask you some questions about your work with Ethicon.

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Do you remember when you first became a paid consultant for Ethicon?

A. As I stated earlier, I do recall, prior to the launch of the product, being part of a focus group in which I was asked to give an opinion on the feasibility of this as a new procedure, and I was paid for that.

Q. And we're talking about the TVT in 1998 or 1999, roughly?

A. To be honest with you, if I had to give you a guess, this was '96, '97. I'm pretty sure it was '96.

Q. And do you recall when you became a proctor for Ethicon?

A. I'm going to say 2002, perhaps.

Q. And did you have a contract for either of those positions, that you're aware of?

A. Well, the focus group, of course, was a single event. The -- at some point in time, there would be a --

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there was probably a contract regarding proctoring. And I recall every year that -- that would be a new and usually different terms.

Q. Do you recall how you were compensated for being a proctor for Ethicon?

A. Yes.

Q. How much were you paid?

A. It depended upon the situation, if I was doing a procedure within my institution, did I have to drive 60 miles, did I get on an airplane. So it would vary.

I would -- I would guesstimate maybe $1,500 at the lower end, $2,500, maybe $3,000. You know, sometimes there would be one person, it might be up to three people. There was probably a factor for that.

Q. So that was per preceptee or group of preceptees that you were paid between $1,500 and $5,000?

A. No $5,000; $2,500, $3,000.

Q. $2,500, I mean.
A. Again, I think the higher end would speak to more than one. The lower end would speak to location and maybe one. There wasn't that significant of a difference, I don't recall. I mean, the highest might have been $3,000.
They would classify you. Maybe, in the beginning they would call me a local proctor. At some point, I was a national proctor. Physicians might fly in from other locations. I would -- I'm assuming that the reimbursement may have been a little higher. I never did a large volume --
Q. Do you know --
A. -- proctoring.
Q. -- offhand how many doctors that you proctored over the years with Ethicon?
A. I don't know offhand the number of doctors I proctored. If I were to throw out a term, like, fifteen, twenty over a -- over a ten-year period

of time.
And the -- in the context of proctor, I'm talking about a physician that was in the operating room with a patient, not necessarily a lab -- you know, a lab situation, a dry lab situation or anything like that.
Q. We have a contract from 2006 that says you would be paid a maximum of $100,000 for the year.
Do you recall how much you were actually paid --
A. In 2006?
Q. -- in 2006?
A. In general, it would probably be something like $12,000, maybe $15,000.
I would say -- I think the highest I had gotten -- and, again, I mean, a total number and this goes beyond -- was maybe $30,000. But I have to tell you, that probably includes more of the design work that I may have done.
Q. So in 2006, your estimation

would be between $12,000 and $30,000 that you were paid by Ethicon?
A. I would say it's probably between $6,000 and $20,000. I don't know for sure. It was not, in my estimation, substantial.

- - -

(Whereupon, Exhibit Toglia-12, ETH.MESH 11843352-364, Consulting Agreement Requisition Form, was marked for identification.)

- - -

MS. THOMPSON: We have this marked as an exhibit. I only have one copy of the contract. I'm not going to ask any more questions about it, but if you want to look at that, that's fine.
BY MS. THOMPSON:
Q. Do you have records of the money that you received from Ethicon for payment for your services?
A. As in payment stubs or -- I

haven't done anything with them recently. I mean -- I mean, there may have been one case in 2013. There may have been none for the preceding several years.
So, certainly, as we go back five or six years, I don't think I would have -- you know, I would have the original invoices or records, no.
Q. When was the last time you proctored a physician for Ethicon?
A. To the best of my knowledge, there was one physician that I proctored who was within my system, and I want to say that was maybe 2013. I couldn't -- I mean, to my mind, it seems like it was longer ago than that.
Q. Between 2006 and 2013, did you believe that you had a contract each year with Ethicon for various services?
A. I believe so. Again, my role with Ethicon changed with time as I looked at different projects or worked on different projects.
Q. We have an Excel spreadsheet

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that shows $30,000 in 2011, $6,000 in 2010 and $15,000 in 2013.
Does that sound about right?
MR. SNELL: Object to the form. Foundation.
THE WITNESS: I believe that that's in the range of the numbers that I had -- that I had recollected.
MS. THOMPSON: And we marked that spreadsheet as Exhibit 13, if you want to look at that.
THE WITNESS: Sure.
- - -
(Whereupon, Exhibit Toglia-13, Spreadsheet, was marked for identification.)
- - -
MR. SNELL: This doesn't have a Bates number on it. Where is it from?
MS. COPE: I can get you the number when we print them out. They're not produced, in Excel

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format, with a Bates number.
MR. SNELL: But it has a Bates number, a document number attached to any native file if it's a produced document --
MS. COPE: And what I'm saying is I can get that --
MR. SNELL: Oh, you can get that?
MS. COPE: -- to you. But when we print it out --
MR. SNELL: I got you.
THE WITNESS: I'll be honest with you, I can't read any of this. But I'm happy to accept the figures you threw out. But please don't ask me to read the details.
I can read my -- I can read my name, I see that, I recognize that.
BY MS. THOMPSON:
Q. So we don't have time to have you try to read that, correct?
Did you ever receive any

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gifts from Ethicon or employees of Ethicon?
A. Not that I'm aware of, no.
Q. Did Ethicon reimburse your travel expenses and travel time while you were working as a consultant for them?
A. Yes.
Q. And were there times that you also gave presentations at dinner meetings for doctors for Ethicon?
A. There might have been. I don't recall that being a common scenario. But I would -- I would venture, yes, there probably were meetings that a presentation -- and, again, I would have trouble separating the TVT stuff from something else.
Q. And I believe we have an invoice in 2009 for a $3,000 speaking stipend for dinner meeting and in 2008, $3,095.95 for a dinner speaking meeting.
Does that sound like that probably happened?
A. I'm a pretty cheap date, so

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it kind of sounds like something that we might have done.
Q. $3,000 for a dinner presentation doesn't sound that cheap to me.
A. No?
Q. Does it to you?
A. Time away from one's family after one has already worked a ten- or twelve-hour day? I'd say that's pretty cheap, but that's just my personal opinion.
Q. And at those presentations, you would typically show a PowerPoint?
A. We may have shown a PowerPoint. It could have been more of an informal discussion. I mean, PowerPoints are usually one of my preferred methods to lead a discussion.
Q. But you don't remember specifically at the dinner meetings that you did for Ethicon whether there was a PowerPoint involved?
A. I mean, recognizing that

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we're in a public restaurant somewhere in Philadelphia, I could see it going either way, based upon the venue.
Q. Do you remember preparing slide presentations for any talks at Ethicon?
A. I'm sure that I have prepared talks. I don't -- I don't recall.
Q. And Ethicon would pay for your travel and meals for those meetings as well?
A. They would pay for travel. I'll be very honest with you, I don't usually bill for meals. I have to eat anyhow, that's not usually something I would bill myself.
Q. I think we already talked about the clinical study agreements that you had with Ethicon for the TVT.
Was there also an agreement for --
A. So, I'm sorry, I didn't -- I don't recall I had a study agreement with

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Ethicon.
What are you referring to?
- - -
(Whereupon, Exhibit Toglia-14, ETH.MESH 03617772, Consultant Invoice Dated 5/28/09, was marked for identification.)
- - -
MR. SNELL: What number is this?
THE WITNESS: 15.
BY MS. THOMPSON:
Q. Do you remember an agreement to provide services relating to the PROSIMATM registry?
A. This was not a study agreement. I think I -- I just simply read material.
PROSIMATM was not a procedure I ever performed or performed clinically. I -- it's a secrecy agreement, which means, I think, they basically talk to me about the procedure. Maybe they had results from a registry

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and I was simply reviewing those results.
But I did not participate in a PROSIMATM study.
Q. Do you remember whether you were paid for whatever service you provided for the PROSIMATM registry?
MR. SNELL: Form.
THE WITNESS: I'll be very honest with you, I don't recall really having any involvement with PROSIMATM.
BY MS. THOMPSON:
Q. Why not?
A. I don't know. I don't know whether -- whether I was -- it was something that didn't meet my clinical interest, whether they decided that they were not in need of my services.
I remember PROSIMATM as a concept. I know there was a clinical trial done. This was not a project that I was active on.
Q. And I can't remember from earlier, did you use the PROSIMATM at

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all?
A. No. That's what I'm speaking to.
Q. In the TVT versus TVT-S study that you participated in --
A. Yes.
Q. -- were you paid by Ethicon --
A. No.
Q. -- for your participation in that study?
A. No.
Q. I believe the disclosure on that article was that you were preceptor -- preceptor for Ethicon at the time the paper was published?
A. Yes, that would be a separate.
Q. Was that the full extent of your employment with Ethicon?
MR. SNELL: Objection. Form. He wasn't employed by Ethicon.
MS. THOMPSON: Sorry, my

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fault.
BY MS. THOMPSON:
Q. Your financial arrangement with Ethicon?
A. I'm sure you understand that the publication occurred years after the actual study was completed. I would think that the disclosure came at the time of submission of the manuscript for publication. So it wasn't during the study.
I mean, I think that my relationship with Ethicon was fairly consistent over those -- over that ten-year period of time.
So I have no reason to -- I hope you understand the differential I'm trying to make, because I'm trying to be accurate.
I assume that I was -- I was a preceptor at the same time -- I mean, I trained some of the -- I trained some of the other investigators in the trial. I'm -- I pretty strongly don't think

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there was -- I charged -- Ethicon did not pay me for any of that nor did they reimburse me for travel. That's just something that I did because these were my colleagues, if that makes sense to you.
Q. Sure. And how many times did you do cadaver labs for Ethicon, ballpark?
A. It could be four. It could be eight. I would say maybe closer to the four.
Q. For what products did you do cadaver labs?
A. You know, oftentimes, because cadaver labs are so expensive to obtain the materials, it certainly was typical that on one day we might have been working with TVT-Secur, we might have been working with PROLIFT®, we might have been -- I'm sure that we worked with Retropubic and Obturator.
Q. Did I ask you how many PROLIFT® devices you actually placed?

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A. You have not asked me that.
Q. I didn't think so.
Could I ask you that question, how many PROLIFT® devices did you actually place?
A. You know, according to the information that I just sort of tracked upstairs here, it was probably in the vicinity of about 400.
Q. And when did you stop using PROLIFT®?
A. Once it was removed from the market.
Q. Are you aware that your website still includes PROLIFT® as an option for women who have prolapse?
A. I am aware. And if I had the time or the knowledge to remove it, I certainly would. But thank you for reminding me of that outdated information.
Q. You're welcome.
Did Ethicon also help you advertise your practice?

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A. There was a brief window of time that Ethicon, in professional education, was interested in helping to raise awareness of pelvic floor dysfunction and the treatments for that.
My -- I only -- I only remember one situation in which we placed an ad in a magazine. I think it corresponded to when I had hired a new partner, and I just was interested in letting people know that our practice had these two physicians.
I don't think that that ran for more than three months. That's my only recollection. It was kind of a, you know, what do you think of this idea, you know. I think we just -- we did it on a one-time basis.
Q. But in addition to the money that you were paid by Ethicon for various preceptor trips, dinner presentations, et cetera, they did provide advertisement for your practice?
MR. SNELL: Objection to

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form.
THE WITNESS: In a sense. I mean, it's not that they paid me and I paid for the ad. Like, with the clinical trials, I didn't get the money, the money was -- would have been -- would go through our channels, that's what the Lankenau Institute of Medical Research does; I believe that they may have been involved with the clinical.
So the money went somewhere. It's not -- not money that I touched, so to speak.
BY MS. THOMPSON:
Q. Going back to something you mentioned a minute ago.
What information did you just check upstairs?
A. I checked in with my wife upstairs, and I looked over my report.
Q. You mentioned that you, after checking the information upstairs, you thought that you had done about 400

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PROLIFT® procedures, that's what I was asking about.
A. Oh, excuse me --
MR. SNELL: That's in his head.
THE WITNESS: It's just --
MS. THOMPSON: Oh, I took it --
THE WITNESS: No, no. I'm so sorry.
MS. THOMPSON: Oh, I took it literally.
THE WITNESS: No, no.
MS. THOMPSON: I'm glad we clarified that.
MR. SNELL: That was taken out of context.
THE WITNESS: My apologies.
BY MS. THOMPSON:
Q. Dr. Toglia, did you ever complain to Ethicon that its business practices affected the income received by your practice?
A. Oh, I'm sure that I may

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have, in frustration, made comments. I've got to be honest with you, I don't think it helped or hurt in a significant sense.
But, occasionally, I might -- might have gotten my feelings, you know, hurt.
Q. Do you remember sending an e-mail to someone at Ethicon about lost business as a result of some of the sales reps activities, Eileen's specifically?
A. I don't. I'm aware of an e-mail, I don't -- can't tell you that I remember, at the time, again, sort of the context.
But, yeah, there was -- there was a point that I was a little grumpy about things. Although I may have been simply misdirecting my frustration in the wrong direction, more than likely.
Q. And was that because they had trained one of your referral physicians who then became a competing physician?

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A. I mean, this is referring to Dr. Finnegan. Dr. Finnegan is a colleague of mine.
I don't -- I see the statement. I understand what that seems to be. I can't tell you that I ever felt like that that hurt my business. I think, really, what I -- the message that I was trying to do here -- the message I was trying to get across here, which I will tell you, at this point, I was completely ineffective, I was simply trying to say, look, if we're going to train physicians, you know, within my department, I would like to be the trainer, in that I would like to have a relationship with people, so if they're doing these procedures and they want advice, I would like to be viewed as -- as someone they could speak to.
And I think that's really what I was trying to get at, although, I admit, I did not state it -- I did not state it well.

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And, to be honest with you, I was being a bit dramatic here. I have a very cordial relationship with Finnegan. I don't think he's had any effect on my business whatsoever.

- - -

(Whereupon, Exhibit Toglia-15, ETH.MESH 10399348, 4/29/09 E-mail from Patricia Beach to Judi Gauld; Subject: FW: PROSIMATM Registry, was marked for identification.)

- - -

BY MS. THOMPSON:

Q. Did Ethicon pay for community education or other events that may have resulted in increased patients or business for you?

A. It was not uncommon -- when you say "paid for," let me, please, just sort of qualify that.

So we would -- from time to time, we would give community education events on the hospital campus. The

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company would provide snacks and refreshments. I don't think that there was ever a situation where I was paid to give that presentation. The presentations, typically, were general presentations; I'm going to talk to you about incontinence, whether that be urge incontinent, whether that be stress incontinence; I'm going to talk to you about prolapse.

Does that make sense? But I don't think I was ever paid -- I was never financially rewarded for that. They simply provided snacks and refreshments in that regard.

Q. Are there -- are any of the awards or recognitions that you received the result of nominations from Ethicon?

A. No, not that I'm -- no. I was never a high priority for them, to be honest with you, given that, you know, we had very well known -- other consultants, I'm sure you must be aware, within a short distance from here. I was kind of

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like -- in that regard, no.

Q. Do any of the committees or organizations or employers have policies regarding conflict of interest or accepting money from industry sources?

A. You're talking --

MR. SNELL: Form.

THE WITNESS: You're talking about my employment?

BY MS. THOMPSON:

Q. Yes.

A. So my employment contracts do have language that allows me to function as a consultant to industry, to publish articles, books, where I might get a royalty.

Q. And the academic institutions with which you're affiliated don't have policies regarding accepting payments from industry?

A. Not as they affect me, since I'm not -- you know, that's usually the case if that's the person who is paying your salary.

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I think it really -- those kind of relationships say, look, you can't sort of double dip. You can't be -- you can't be getting paid as a physician and, simultaneously, at that same time.

Q. Have you disclosed your financial relationship with Ethicon to committees that you've served on, for example, AUGS?

A. Of course. We're very transparent. I mean, the public is aware. I mean, you've got The Sunshine Act. There are -- there -- certainly it's public knowledge.

It's also public knowledge what, you know, CMS has paid me, which is Medicare.

Q. And you've disclosed your conflict of interest with Ethicon on all your publications since the time that you began working for Ethicon?

MR. SNELL: Form.

THE WITNESS: I don't work

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for -- I never worked for Ethicon. I don't --
BY MS. THOMPSON:
Q. Doing work for Ethicon?
MR. SNELL: Same objection.
THE WITNESS: I have done -- I have done contractual work with Ethicon. I don't know what I -- I don't have any responsibility to report to them what I publish or what else that I do.
BY MS. THOMPSON:
Q. Do you disclose the work that you do with Ethicon to residents that you're teaching?
A. Yes.
Q. Has Ethicon ever asked you to attend society meetings and give presentations or be represented at exhibitions at the society meeting?
A. I don't believe I've ever done anything like that for Ethicon.
Q. Dr. Toglia, did you have a sexual relationship with Kathleen Feeney?

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A. No.
MR. SNELL: Objection.
BY MS. THOMPSON:
Q. Did you have an affair with Kathleen Feeney?
MR. SNELL: Same objection.
THE WITNESS: I don't know what you're referring to.
BY MS. THOMPSON:
Q. Did you have anything other than a professional relationship with her?
MR. SNELL: Same objection. Argumentative.
THE WITNESS: You know, I mean -- you know, we were friends, in a sense, although it's not a friendship that extended beyond, like, when she left the company. It quickly, you know -- I don't know where you're coming from. This -- Kathleen Feeney is --
- - -
(Whereupon, Exhibit

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Toglia-16, ETH.MESH 11838868-869, 5/30/07 E-mail from Kathleen Feeney to Cindy Pypcznski; Subject: FW: Surgery at Lankenau, was marked for identification.)
- - -
BY MS. THOMPSON:
Q. Did you -- did you -- do you recall an e-mail when she was leaving the company in which she provided you with her personal e-mail address?
A. I know that Kathleen Feeney was interested in me, perhaps, writing a letter of recommendation. I know that she had asked me could she have -- could I be a reference, and in that context there may have been.
Q. Do you remember asking her what she would use as her name when she left Ethicon. And she said -- replied Kath Toglia?
A. I -- Kathleen would make offhanded comments from time to time. I can't say I can't remember her ever

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saying that. But I wouldn't be surprised. She was teasing me at the time, of course.
MS. THOMPSON: I think that's all the questions I have for you. Thank you, Dr. Toglia, for your time.
MS. COPE: Sorry, just wanted to clarify. That one document that didn't have the Bates number, I got the Bates number, if you want to stick that on the exhibit.
MR. SNELL: Let's go off the record.
VIDEO TECHNICIAN: We are off the record. The time is 8:10 p.m.
- - -
(Whereupon, a brief recess was taken.)
- - -
VIDEO TECHNICIAN: This marks the beginning of Video

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Number 5. We are back on the record. The time is 8:17 p.m.

- - -

EXAMINATION

- - -

BY MR. SNELL:

Q. Dr. Toglia, we're back. I just have a few follow-up questions, following up on plaintiffs' counsel's questions to you.

First of all, I believe you were trying to explain your methodology to plaintiffs' counsel.

Can you state your methodology that you utilized in assessing the utility and the safety of the TVT device for its intended use to treat stress urinary incontinence?

A. Yes. So the question that was put before me is whether or not the TVT was well suited for its intended purpose, which was the treatment of stress urinary incontinence in women, whether or not that -- it achieved that

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intended use, whether or not that was -- the device was safe for that use.

In order to formulate that opinion, I reviewed the highest levels of evidence that I could find. As I stated earlier, the highest levels of evidence would include things like randomized control trials, systematic reviews or meta-analysis and, fortunately, there was a tremendous amount of data.

Just right behind that would be things like long-term registry studies, the data that came from closed health systems and the like.

I would add that the societal guidelines position statements, which are -- in essence, is a different type of a committee that would have done their own systematic review and then formulated an opinion in the same manner. Those are the type of things that I would look at myself.

In addition, I looked at the documents provided to me concerning the

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internal Ethicon communications. I looked at some of the -- the expert opinions provided by the plaintiffs' side. We looked at, you know, animal studies, in vitro studies. Although, again, recognizing that those are really Level 5 evidence data, that you really can't draw any clinical inference or -- or application directly to the TVT device. Those were looked at as well.

Q. You saw that plaintiffs' experts cited to a bunch of hernia documents, prolapse documents, animal studies in their reports?

A. Yes, I saw that. Yes.

Q. And I believe you earlier told plaintiffs' counsel you were shocked at their methodology; is that accurate?

A. I would -- I would --

MS. THOMPSON: Object to form.

THE WITNESS: I was -- I did not find their methodology to be scientifically rigorous. They did

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not seem to include the Level 1 studies, randomized control trials. They did not refer to the systematic reviews.

Their focus seemed to be largely on very low-level, almost insignificant things that really had no direct application to the TVT design, safety or the device when it's used in its intended manner to treat stress urinary incontinence.

BY MR. SNELL:

Q. So for these hernia documents or hernia studies that the plaintiffs' experts, like Dr. Elliott, seem to cite on every page of his report, would those even fit on the evidence pyramid, if one was to do a proper methodologic scientific review to assess the safety of TVT for its intended use to treat stress urinary incontinence?

MS. THOMPSON: Object to form.

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THE WITNESS: Within the -- within the context, those would not figure as well. Those would usually be discarded as being not relevant to the TVT sling, the device or its design.

BY MR. SNELL:

Q. You brought these evidence pyramids.

MR. SNELL: I'd like to mark them as exhibits.

- - -

(Whereupon, Exhibit Toglia-17, Level of Evidence Chart, was marked for identification.)

- - -

(Whereupon, Exhibit Toglia-18, Level of Evidence Pyramid, was marked for identification.)

- - -

BY MR. SNELL:

Q. Doctor, Exhibits 17 and 18,

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are those the level of evidence pyramids you brought?

A. Yes.

Q. Are those important in conducting a proper -- strike that.

Is utilizing the highest levels of evidence important in assessing the question, is the TVT reasonably safe for its intended use to treat stress urinary incontinence, in your opinion?

A. Absolutely. I mean, the foundation of any systematic review is to start with your highest level of evidence. If you have the highest level of evidence, then the lower levels of evidence typically are not given weight.

Certainly if they are incongruent -- if the lower evidence -- levels of evidence are incongruent with the higher levels of evidence, it just simply validates and verifies the uselessness of those articles.

Q. And I believe you testified your methodology was to look at the

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highest levels of evidence --

A. Of course.

Q. -- and not just one document -- strike that.

Not just one guideline or randomized control trial but numerous ones?

A. We looked for consistency of the levels of evidence -- excuse me, we looked for consistency of the independent analyses that had similar levels of evidence.

Q. And did you find consistency in the systematic reviews and meta-analyses that were Level 1 evidence, such as the shunt 2014 SGS study or paper and the AUA guidelines that did a systematic review?

A. They're all very consistent speaking to the safety -- long-term safety, long-term effectiveness of that device.

Q. On Page 18 of your report, you talk about the safety and surgical

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re-intervention being well studied, utilizing national and regional closed systems.

Do you see that at the top?

A. Yes, I do.

Q. That's something you were talking to the plaintiffs' counsel about, the significance of the closed systems.

Do you recall that?

A. Yes, I -- I started to discuss that. And the point I was trying to make is that the advantage of the -- you know, certainly one of the concerns about following patients or looking for complications is, what's your degree of follow-up and whether or not those patients are somehow excluded. That's where concerns that relate to things like selection bias could come from.

The advantage of looking at data, whether it's Medicare data, like the Thomson Reuters MarketScan data, Kaiser, Canada, some of the other countries, is that people, you know,

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don't drop out of the system and they are able to capture, with a high degree of accuracy, what happens to these individuals over time.

Q. And in Pages 17 through 21, do you identify some of those studies that you reviewed and found to be scientifically reliable and high levels of evidence?

A. Yes, they are -- and they are consistent with the Level 1 data and the systematic reviews.

Q. Earlier, plaintiffs' counsel asked you some questions about the AUGS position statement.

Do you recall that in general?

A. Yes.

Q. Can you turn to that? I just have a few follow-up questions. I believe it was in one of these multiple binders.

A. Less than one minute, sir, I have it right in front of me.

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Oh, I have to apologize. Okay.

Q. Remember plaintiffs' counsel asked you some questions about the AUGS/SUFU position statement and whether it had any discussion about safety or complications?

A. Yes.

Q. Take a look at Paragraph Number 2.

Does the AUGS/SUFU statement have any discussion about an assessment of whether the TVT or midurethral sling is safe?

Sorry, numbered Paragraph 2, unless I'm --

A. Numbered paragraph. Oh, I'm sorry.

Number 2 which starts, The monofilament polypropylene mesh is the most extensively studied anti-incontinence procedure in history.

So, yes, this particular paragraph -- and the references are

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provided, and I would point out that the references cited do consist of high-quality levels of evidence, which talks about the fact that -- that this particular procedure had been studied as long in follow up than any other procedure and seems to demonstrate superior safety and efficacy.

Q. If you look at Reference Number 8, under Paragraph 1, where it talks about the lightweight monofilament polypropylene sling has demonstrated long-term durability, safety and efficacy for up to 17 years, are they referring to the Ethicon TVT Retropubic sling that assessed?

A. Yes. That refers to the Nielsen long-term prospective cohort that, I believe, looked at, over a 17-year period of time, a group of approximately 90 individuals.

Q. Does that AUGS/SUFU position statement, is it reliant upon Level 1 evidence like Cochrane reviews or

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randomized control trials?

A. Yes, it is.

Q. One of the end notes in the overall assessment of the slings is Cochrane review by Ogah, et al.

A. Yes.

Q. Is that a study that you're familiar with?

A. It is. But that's a meta-analysis.

Q. And what is the significance of that type of meta-analysis and being a Cochrane review, if anything?

A. Sure. So a meta-analysis seeks to look at as much of the relevant literature. As well, it will -- it will take all of the randomized control trials, it will sort of combine the data, in a sense, for analysis. It will draw comparisons to the other procedures or the other approaches.

Q. Okay. And do those references that the AUGS/SUFU position statement rely upon for the statements in

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that assess the complications with TVT?
A. Yes.
Q. Such that -- and I believe you talk about, in the Ogah study, in your report, you discuss that that Cochrane review discusses multiple complications?
A. It does.
Q. Including that the monofilament and macroporous mesh, like TVT Retropubic, in the treatment of stress urinary incontinence has a lower rate of exposure than the multifilament meshes.
Do you recall that from the Ogah Cochrane review?
A. Yes. And I believe that the majority of the studies that were included in that analyses would have been specifically with the Retropubic TVT device.
Although, there was another part of the analysis that would have looked at the Obturator approach as

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compared to the Retropubic approach.
Q. Considering that this AUGS/SUFU position statement, as you have testified, relies on Level 1 systematic reviews and other data, do you believe it is reliable?
A. Absolutely.
Q. Some questions were asked to you -- strike that.
And do you believe that the other position statements and the stress urinary incontinence systematic reviews and guidelines by SGS, the American Urologic Association, IUGA, and others, are also reliable?
A. They are -- they are reliable and they're incredibly consistent with each other.
Q. You were asked some questions about complications your patients may have had and how plaintiffs' counsel, what documents she would go to --
A. Sure.

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Q. -- to look for that.
My question to you is this: Did you track your patients' complication rates over time with the TVT Retropubic device?
A. Yes, we did.
Q. How did you do that?
A. We kept notes on the patients. I mean, most -- you know, when you're dealing with a procedure that, in our hands, had complication rates in the single digits, it's not that hard to make the mental note, you know, that, you know, we saw two episodes of bleeding that required observation.
Q. Did you counsel your patients on your rates of complications you had with the TVT Retropubic device over time as you gained experience?
A. Yes. I felt an obligation, certainly, as somebody that was well respected in this field and somebody that was able to offer several different options to my patients in this, that we

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would talk to them, again, sort of about our personal experience.
You know, when you -- when you work out in the community and you take care of women in the community and you're not necessarily at a university hospital, I have found that women are very much interested in what your personal experience was.
Obviously, we were very fortunate to have a high volume of cases. And within that context, I could say to them, you know, regularly, look, I've done 500 of these and, you know, the complications that we have seen are -- you know, there have been occasional episodes of bleeding from time to time, either during or after the procedure, things of that nature.
Q. And so when you put in your report, for example, your complication rates, in your hands and -- for example, that your rate of bladder perforation with the TVT Retropubic decreased over

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time as you became more experienced, are those reliable rates?
A. Yes.
Q. Are those based on your firsthand observations and tracking of your complication rates over time with the TVT Retropubic device?
A. They are.
Q. You talked to plaintiffs' counsel about your various different design expertise and work you did with Ethicon on many different products.
Do you recall that?
A. I do.
Q. One thing I want to ask you about, I didn't recall if you said it or not, but do you recall the GYNEMESH® M, the ULTRAPROTM mesh product that was used in PROLIFT®?
A. I do.
Q. Do you recall --
A. That was used, excuse me, in PROLIFT® +M.
Q. PROLIFT® +M. Thank you for

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your correction.
A. Sure.
Q. Do you recall that you were actually one of the surgeons that did the design validation of the GYNEMESH® M mesh, assessing the suitability, safety and efficacy and adequacy of that design?
A. I did participate in some kind of a design validation study, yes.
Q. Do you recall assessing the IFU for that device during the design validation?
A. Yes, I do.
Q. And whether you were asked, is the IFU, clear, cohesive, accurate, do you recall that?
A. Yes.
Q. And did you give opinions to Ethicon in that design validation for the GYNEMESH® M device?
A. I provided them with, you know, constructive feedback.
Q. Some questions were asked of you, I think, about pubovaginal sling

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exposures or wound complications with the Burch.
I want to hand you the Schimpf paper.
And, actually, first of all, do you have your report handy?
A. I do.
Q. Turn to Page 19, on the second paragraph, where you discuss wound complications occurring with the Burch and autologous fascial sling.
Do you see that?
A. The -- you're referring to Novara, et al.?
Q. I'm right here on Page 19?
A. I'm sorry. Yes.
Q. So in the Schimpf -- I put before you the Schimpf SGS systematic review and meta-analysis.
Is that a document you're familiar with?
A. Yes, it is.
Q. Is that a document you reviewed and rely upon?

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A. Yes, it is.
Q. Is that a document that's reliable, in your opinion, to scientifically assess the safety and utility of the design of the TVT Retropubic device?
A. It's a very reliable device -- very reliable document.
This is what -- this is what we were speaking to Level 1 evidence. This is a systematic review -- an independent systematic review.
Q. And the Society of Gynecologic Surgeons, do they have a good reputation within the field of female pelvic medicine?
A. Absolutely.
Q. Do you actually belong to that society?
A. I serve a leadership role. I serve on the executive committee for that society.
Q. And in your role and participation with the society -- let me

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ask you this: Before I contacted you and asked you to analyze the data, had you already been reviewing and analyzing data on the TVT Retropubic device?
A. Yes.
Q. Had you been reviewing data and analyzing data, the different levels of data, on the TVT Retropubic device going back all the way to when you began considering to use it?
A. Yes. Absolutely.
Q. So let's look at the Schimpf systematic review and meta-analysis.
Does that study -- strike that.
Looking at the Schimpf systematic review -- review and meta-analysis, does that Level 1 systematic review inform you of wound complications and other problems that can occur with the Burch and the pubovaginal sling?
A. It does.
Q. In the table in the Schimpf

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paper, does it identify whether patients with pubovaginal sling or Burch have wound infections, exposure and return to the operating room for erosions?
A. Yes. Table 3, specifically, addresses the analysis that would look at -- and, again, this was exclusive of -- excuse me, this was inclusive of randomized control trials.
So this is a -- this is a summary of the analysis of Level 1 data.
Q. And did the Schimpf systematic review, the summary of Level 1 data, identify that the Burch and the pubovaginal sling had exposures or return to the operating room for erosion?
A. Yes.
Q. Did -- go ahead. I'm sorry.
A. So, specifically, it analyzed the number of studies and the incidence of, say, exposure between three different types of midurethral slings, the traditional, pubovaginal vaginal and the Burch.

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It also looked at return to the operating room specifically to treat -- to treat erosions as well. It looked at wound infections, hematoma, dyspareunia, various organ injuries.
Q. Did -- did that inform your opinions on the safety of the TVT device for the intended use of the treatment of stress urinary incontinence?
A. Yes. And, obviously, as you can imagine, I was very reassured by the fact that it was both consistent with my experience, having performed, you know, each of these procedures, and also confirmed my experience and my own review of the literature of the safety and long-term efficacy of this procedure.
Q. You mentioned earlier that there was consistency in the Level 1 data and the longer-term studies, the prospective database studies.
Why is that important in conducting a proper scientific methodologic analysis of the question, is

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the TVT safe for its intended use to treat stress urinary incontinence?
A. Well, objectivity. You know, the reasons why one designs a randomized control trial is that we're trying to eliminate everything from selection bias, having patients that might be sicker in one arm versus the other, more comorbid conditions, variations that might relate individually to a certain -- a particular surgeon or institution.
Q. Plaintiffs' counsel asked you about degradation, and I believe you told her, numerous times, that you didn't believe that the TVT degraded; is that correct or not?
A. Within the clinical use of the TVT for the treatment of stress urinary incontinence, there -- I'm not aware of any reliable data suggesting that there is degradation.
Q. The plaintiffs' counsel asked you a question about were there any

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studies that -- I think the question was, and it may have been a double negative -- that did not show oxidative degradation.

Do you recall questioning on that?

A. I do. And the more that I thought about it, I realized that I did address that in my report.

Q. Can you turn to Page 26 of your report?

A. Yes.

Q. There was a paper that the plaintiffs' experts pointed to by Clave.

Do you -- have you read that paper?

A. I'm familiar with that study.

Q. And, first of all, is that study a reliable study to assess, scientifically, the TVT and, in particular, for its intended use to treat stress urinary incontinence?

A. I mean, I don't believe that the Clave study looked specifically at

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the TVT device, per se. So it was a low-level observational study, in vitro, in a sense, in that the -- in that the material was analyzed under a scanning electron microgram and some chemical analysis.

Q. And I believe you earlier testified, for the intended use of treating stress urinary incontinence, is Clave one of the studies that wouldn't even make it onto the level of evidence pyramid because it doesn't specifically focus on the intended treatment of stress incontinence?

A. I don't believe that Clave would be considered in that kind of high-level evidence analysis, in terms of the clinical utility, safety or design of that device.

Q. So back to my earlier -- the reason why I brought you to this study or asked you about it, plaintiffs' counsel asked you about direct oxidation.

Even with all the

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limitations and the poor methodology in the Clave study, did they document that they can show oxidation of the polypropylene?

A. They comment directly upon that. Again, you know, oxidative degradation is a chemical reaction typically reserved for enzymatic changes to, say, amino acids.

Again, as I think I stated earlier, it simply involves the insertion of oxygen between carbon -- you know, between carbon molecules within a compound. In that concept, you know, polypropylene is not an amino acid or an organic compound.

But the authors do very specifically state that they were very limited in how they could respond to here -- they say -- they say here that, you know, look, we have to acknowledge that while we offer an opinion -- we offer hypotheses that, maybe, what we're seeing in terms of changes could be the

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result of oxidation. They said, look, we can't confirm this hypothesis, based upon our methodology or our analysis, whether or not direct oxidation would actually have occurred in vivo.

Q. So you saw they did some analytical chemistry testing on a limited number of samples in the Clave paper, and even with that methodology, they were unable to confirm their hypothesis; is that right?

MS. THOMPSON: Object to form.

THE WITNESS: Again, you know, they -- the way that Clave was set up is they looked under -- under a scanning electron microscope, very, very high power. You know, here is the pristine material, here are these -- these expanded small fragments of material.

In that paper, if I'm -- if I'm correct, their only definition

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of degradation is this doesn't look like this.

And, you know -- and they did not see changes in all specimens. In fact, they saw changes only in a minority of those implants analyzed. And, you know, again, you know, they said, look, we acknowledge that we cannot determine whether what we observed somehow altered mechanical properties. They acknowledge that they could not analyze implants that were in women that had not gone back to the operating room to have a portion removed for some clinical indication.

And, certainly, my opinion would follow that as well, simply the observation of surface crack, the minority of specimen does not establish that degradation does occur.

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And, again, as I've stated over and over, you know, that it's unlikely that this could have any kind of mechanical or functional outcome. But, more importantly is, again, you simply can't infer. You can't clinically infer from a paper such as this, which is just sort of an observation to any kind of effect that it might have when it's used for its typical indication.

BY MR. SNELL:

Q. And with regard to the oxidation question, looking at the article, at the bottom of Page 266, it states, Several hypotheses concerning degradation of polypropylene are described below. None of these --

A. Counselor, I'm sorry, I'd like to follow along with you.

Q. I'm sorry.

A. I'm sorry. Go ahead.

Q. You can just take it.

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I guess my question for you is, at Page 266, you had mentioned that the authors acknowledged that what they were doing was basically hypothesizing; is that correct?

A. Well, I mean, you know, the authors did make an observation that the material had a different external appearance, albeit under only, you know, very high powered scanning electron microscopy. And then they start to come up with some ideas that might potentially explain it.

And they said, look, you know, we've talked about several hypotheses concerning whether or not, you know, this represents degradation. Again, their definition of degradation is, this doesn't look exactly the same as the pristine state.

And they say, you know, none of these hypotheses, particularly they point out the hypotheses of oxidation, could possibly be confirmed in this

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study.

Q. You were asked some questions about whether there is an immunologic reaction, whether there's severe chronic inflammation -- you were asked some questions, Doctor, about whether there was immunologic reaction to the TVT polypropylene mesh device.

And I believe one of the things you stated was that the randomized control trials, the Level 1 evidence, the long-term data do not show any type of immunologic response in your opinion.

Is that correct or did I misstate that?

A. No, the majority of the studies, the five-year data and ten-year data, you know, where they said, look, we did not observe one instance of clinical inflammation, chronic inflammation, erosion, you know, that speaks to the safety and the lack of a significant adverse immunologic reaction.

And, again, I think just --

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as a scientist, as a surgeon, what I would speak to distinguish between are, you know, reactions that the body has that are of no clinical consequence, reactions that the body has that could result in an adverse clinical outcome.

Q. Do you have Dr. Rosenzweig's binder over there somewhere?

A. In my left hand, I have his expert report. Below me, we have a binder labeled, Company Documents, Rosenzweig.

Q. Let me -- Doctor, if you go back to the middle of -- I know you have a lot of materials in front of you. But go back to the pile. Under -- I think it's under your report, where you were looking at the Schimpf paper as one of the exhibits. Here.

Can I take a look at that, Doctor?

Let me ask you this: Do you remember, you were asked a question about the Wang study by the plaintiffs'

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counsel, if you read it and its methodology.

Do you recall that?

A. I have the Wang study here.

Q. Okay. And you were going to try to answer plaintiffs' counsel's -- strike that.

You wanted to make a statement or give your impression of the methodology of the Wang paper; is that correct?

A. Yes. I offered an opinion, and I wanted to explain my methodology.

Q. Please go ahead and do that.

A. Wang published a -- we would consider -- I mean, he calls this a prospective case-controlled pilot study.

Now, you know, within the world of study design, you know, case controlled studies are, by definition, retrospective, not prospective. Again, case controlled studies are a much lower level of evidence. If we look at the information that I provided here, a

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typical case controlled study is a Level 3.

Now, what's incumbent upon a case controlled study is that you have a very appropriate control group for that study. And the reason for that is that you're trying to minimize selection bias and other forms of bias that could be introduced. And so, as an investigator, you have to be sure that you're picking a group that is representative of your control.

If one group has a certain outcome and you're trying to look at the cause for that outcome, the other group needs to have similar exposure but not the outcome.

So, for example, everyone has a sling, the control group has a sling with -- but lacks the particular adverse outcome you're looking for, whereas the affected group has that outcome, itching, let's say, okay?

Unfortunately, for some

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reason, the investigators chose a control group that consisted of only about seven women. And, again, this was a study of 700 women that had undergone a procedure. And these were not -- these were not control women, these were women that did have a clinical problem that would involve a removal of the portion of the mesh so it could be compared. But that's not an appropriate control group.

So I look at this study and say, you know, in all fairness, this is a case series as opposed to a case controlled. And, you know, that does knock down the level of evidence from a 3 to, actually, now a Case 4.

And, again, the reason why I make that determination is that, you know, we're trying to determine whether or not we can infer clinical outcome, clinical importance. And, again, as we go down on the scale of evidence, you cannot make that inference.

Q. And in that study, because

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of the limitations of that study, can you make that inference with the Wang study?
A. No. You can't make that inference with the Wang study.
Q. Does a study like the Wang study provide scientifically reliable information on the rate of the complication -- I'm sorry, the incidence of complication?
A. Sure. So that's the other thing that -- that, you know, a well-schooled academician would tell you, is that you don't calculate prevalence or incidence based upon a case-controlled study.
Q. And for the case series, like the Abbott paper that plaintiffs' counsel asked you about earlier, do those also allow someone to scientifically reliably speak to what the incidence of a complication is?
A. In the Abbott trial, I think the authors correctly pointed out that, because they could not place a

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denominator, that you could not really speak to incidence.
Q. Do the systematic reviews, meta-analyses, numerous five-plus year data that you referenced show consistency in the overall safety and efficacy of TVT?
A. They do.
Q. You earlier mentioned that all of -- all of that data, and you cited hundreds of different papers, I believe, in your report, shows that the PROLENE® polypropylene Type I macroporous mesh in TVT for the intended use to treat stress incontinence is the most biocompatible.
What did you mean by that?
A. Biocompatible, you know, sort of a synonym for that, you would say it shows good host tolerability. That it was capability of existing within host tissue with minimal to no adverse reaction.
Q. You were asked questions about the Burch and the autologous

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fascial sling.
Are either one of those medical devices?
A. They are not medical devices, they are surgical techniques.
Q. So the Burch and autologous fascial sling are not alternative devices to the TVT, which is a device?
A. They are not alternative devices to the TVT.
Q. You were asked questions and shown an MSDS, material safety data sheet, on bulk polypropylene.
A. Yes.
Q. Is that MSDS sheet relevant or clinically scientifically reliable to assess whether the TVT Retropubic device is reasonably safe for its intended use to treat stress urinary incontinence?
A. No. That would be a conclusion that you would get based solely on your Level 1 levels of evidence.
Q. Would the MSDS sheet even be

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on the levels of evidence?
A. They would not.
Q. You made -- you were asked questions about cancer, sarcoma.
Do you recall that?
A. I do recall that. I do believe that I addressed that in my report.
Q. At Pages 25 and 26, it looks like you addressed those issues; is that correct? At the bottom of 25?
A. Yes.
Q. And in the MSDS sheet, it talked about sarcomas in rats where the polypropylene was in disc or powder form.
Do you recall that?
A. Yes, I do.
Q. And you made a statement about how those data are not pertinent or relevant to the TVT in its configuration to treat stress urinary incontinence as a knitted macroporous mesh?
A. Yeah. The point that I was trying to make, and I don't think I

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stated it very eloquently, is that the investigations that have looked into such claims had focused on the fact that it's really the material composition, it's not polypropylene, per se, but the composite material.

And additional studies were done, following those initial ones, that showed, really, no risk of sarcoma formation.

I mean, again, as a physician and scientist, these concerns have been addressed by my peers. There's -- number one, to the best of my knowledge, there's never been a reported case of a sarcoma occurring in a patient with a TVT.

As I stated that, you know, polypropylene has been a material of choice for 40 to 50 years. And in that context, there are no cases in women. And my opinion was that, you know, concerns about potential carcinogenesis in women really are not substantiated,

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based upon this clinical experience and the established literature.

Q. And you cite to a paper by King and Goldman, where they did an analysis of the Cleveland Clinic's use of thousands of slings over a long period of time.

Do you recall that?

A. I recall that paper.

Q. Was that one of the papers you relied upon for your conclusion that the TVT PROLENE® polypropylene macroporous Type I mesh does not cause cancer or sarcoma in its intended use to treat stress urinary incontinence?

A. That's correct.

Q. Plaintiffs' counsel asked you questions about roping and curling and the mechanical testing of the mesh.

Let me ask you, you -- I think you told plaintiffs' counsel this, you've seen the testing where they put the TVT -- or they put some kind of mesh on a bench machine and stretched it?

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MS. THOMPSON: Object to form.

THE WITNESS: Yes.

BY MR. SNELL:

Q. Doctor, have you seen that -- have you seen testing like that?

A. I've seen the reports on the testing like that.

Q. And photographs like the photographs in Dr. Elliott or Rosenzweig's report, where he put in there a piece of mesh that was clamped and it didn't have a sheath or any instruments.

Do you recall that?

A. Yes.

Q. All right. My question to you is, is that photo and the testing of the mesh in that manner scientifically reliably pertinent to the use of TVT and, in particular, its safety in the intended treatment --

A. It's out --

Q. -- of stress urinary

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incontinence?

A. I mean, it's outside the intended use. So, no, it's not relevant.

And, as I stated, you know, the mesh is delivered protected beneath the -- a sheath. Those forces are not directly exerted on the mesh itself.

Q. And is that --

A. But it's specific to the tension-free design, which is where the name TVT comes from, tension-free vaginal tape. And that speaks to the design and the method in which it's placed.

Q. And in your report, I believe you talk about the importance in the design characteristics of the sheath and what it does?

A. Sure. I mean, that was very important in the design.

And I would point out that's, you know, -- subsequent developments along the area of anti-incontinence procedures all pretty much kept that element of the design

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intact.
Q. And you had mentioned the sheath was important, very important, in your opinion to plaintiffs' counsel; is that correct?
A. Yes.
Q. Why -- so is the sheath a very important design element of the TVT for its intended use to treat stress urinary incontinence?
A. It's elemental in the design. Without the sheath, you would not have a TVT device.
Q. Okay. And having placed, you know, well over 1,000 TVT Retropubic devices, did you find the sheath to be integral or elemental in the use of that device to treat stress incontinence as you were utilizing it?
A. Yes. You know, again, the sheath provided several key elements. One is that it protected the sheath from exposure to the surrounding tissue, to bacteria.

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But I think that, you know, certainly, its greatest utility was to prevent the sheath from changing its configuration.
Q. Plaintiffs' counsel asked you a bunch of hypothetical questions about pore were collapse and curling and fraying and things like that.
You recall seeing those terms mentioned in the plaintiffs' expert reports?
MS. THOMPSON: Object to form.
THE WITNESS: Yes, I do.
BY MR. SNELL:
Q. You saw where Dr. Elliott, and others, would cite to some paper by Dr. Klinge in a hernia application or a rabbit or a mouse study, different data for those theories they were espousing, correct?
MS. THOMPSON: Object to form.
THE WITNESS: I'm familiar

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with the articles in which portions of mesh, we'll call them sheathless mesh, mesh without sheath, were applied in those applications.
BY MR. SNELL:
Q. Those types of documents and that -- I'll call it data or information the plaintiffs' experts relied on, do you find that information scientifically reliable for assessing the question, is the TVT suitable or reasonably safe for its intended use --
A. It's certainly not clinically relevant --
Q. -- to treat stress urinary incontinence?
A. -- to the design of the TVT as it's used for its intended use, no.
MR. SNELL: Let's go off the record. Let me see. I think I may be done.
VIDEO TECHNICIAN: We are off the record. The time is 9:05

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p.m.
- - -
(Whereupon, a discussion off the record occurred.)
- - -
VIDEO TECHNICIAN: We are back on the record.
BY MR. SNELL:
Q. And I believe, per your earlier testimony, Doctor, those animal studies or hernia studies, or documents, are not even on the level of evidence if we were trying to look to scientifically reliable relevant evidence to the application of treating stress incontinence; is that correct?
A. They are -- you are correct. And they certainly don't speak to the safety of the procedure.
Q. Last question.
Do you have Exhibit 4? Plaintiffs' counsel asked you some questions about this e-mail with Kathleen Feeney, and she insinuated that there

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was -- the statement -- here I'll give it to you.
A. Thank you.
Q. -- "can you do her downstairs" had to do with some type of sexual interaction.
MS. THOMPSON: Object to form. That's not what I insinuated.
BY MR. SNELL:
Q. Can you tell, having had time to look and think about this --
A. Sure.
Q. Tell us what, if anything, you believe this pertains to.
A. So Kathleen Feeney had referred either friends of hers, or someone, when they found out what they did for a living, might say, you know, I'm a woman who suffers with stress incontinence, I know you're in this field, what -- which of your doctors would you recommend that I see. She would -- she would give my name and

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number to them. These people would come to see me as a patient.
And oftentimes I'll say, look, I'd say, how did you come to find me. And they would say, you know, my friend, Kathleen, referred me to you because I have stress incontinence and she says that you're somebody that I would feel comfortable doing my surgery.
So in that context, the more that I think about it, a friend of hers, Christine, saw me, and it was a patient that I was going to do her sling for her. My office is on the fourth floor. OR is downstairs. Obviously, I operate at two different hospitals. My recollection is that the friend was closest to that office.
So the comment there, clearly, to me, was, you know -- you know, I talked to her about options, and she kept saying, yeah, I want -- I want that procedure that my friend, Kathleen, has mentioned to me. And so she just

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might have responded, I can do you downstairs.
Now, to the best of my recollection, Kathleen Feeney had two children of her own. I may have teased her from time to time, that, so, hey, you know you're going to need a sling, right? So who are you going to have, you know, do your sling? And she would say, gee, I don't know, Dr. Toglia, I might have you do me, or I might have Dr. So-and-so do me, again, in references to doing her sling.
Q. Did you feel harassed when you were asked those questions by plaintiffs' counsel?
A. I was very much harassed. And I tried to do my best to stay as professional as possible in that regard.
Q. The Ogah -- I want to switch gears, and just, actually, get back to the data.
A. I'm starting to feel like Hillary Clinton here. But go ahead.

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Q. I want to go back to what you did, reliably assessing the data.
The Ogah Cochrane review that was marked, and I'm just referencing Exhibit-5 to Dr. Blaivas's deposition, does that study -- strike that -- does that Cochrane review support your opinions?
A. It certainly does.
Q. Does that study speak to and document, in a reliable scientific Level 1 evidence method, of the lower morbidity and the high safety to the TVT?
A. Again, The Cochrane Group, which is an independent group of researchers, physicians, scientists, people with interest in this area, they conduct independent -- it's an international group of individuals. It's not like there's, like, an office that you would go to and this is the Cochrane office. There's -- it's sort of a group of individuals with common interests and they perform very high -- high-level,

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high-quality levels of work. They are widely regarded as one of the reliable sources for this type of Level 1 data.

And, exactly, their -- their conclusion is that the minimally invasive synthetic slings, and, again, specifically, they looked at TVT data, does appear to be as effective as the other procedures currently being practiced.

Their observation was that there seems to be fewer perioperative complications. And they went on to list specifically which ones, as well.

Q. Is there a more recent Cochrane review that assesses the usefulness, utility, efficacy and safety of the TVT?

A. I believe earlier this year, led by a gentleman by the name of Ford. In 2015, they updated this, I believe, that -- one of the reasons for this is at the time of the original evaluation, there weren't -- there wasn't a lot of

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good quality data on, say, laparoscopic Burches. You know, again, the thing that was unique about the TVT, it was minimally invasive.

They really were hoping to compare it to a more similar minimally invasive. It was felt that the tradition pubovaginal sling, Burch procedures were more invasive.

So as they gathered more data, they were able to compare the retropubic TVT to the laparoscopic Burch. At the same time, there was better quality data being generated with regard to transobturator approach and the mini sling as well.

So, again, they drew a comparison between the retropubic midurethral sling, specifically TVT, and the other two approaches.

Q. You mentioned, I think you said, the NICE guidelines, a little earlier in your testimony?

A. NICE, I would pronounce it

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NICE. It stands for the National Institutes of Clinical Excellence. That, actually, I believe, is a government organization in the UK, a group of epidemiologists and other experts that seek to independently evaluate everything from medication to behavioral therapies across the field of medicine, as well as surgical interventions.

And those recommendations are typically conveyed to the physicians that are within the UK system.

Q. Is that a document that you reviewed and considered in formulating your opinions?

A. I did. I mean, I hold that document in the same light as I do the other systematic reviews.

Q. I'm going to hand it to you. And I want to mark it for the record.

But the -- you said NICE or is it NICE? I'm sorry?

A. I'm going to call it NICE.

Q. The NICE guidelines says,

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Use procedures and devices for which there is current high-quality evidence for efficacy and safety.

And it's got a Footnote 11. And it says, The guideline only recommends the use of tapes with proven efficacy based on robust RCT evidence.

What does that mean?

A. That's what I've been speaking to, that, you know -- once you have high-quality, high-level of evidence, you can pretty much draw your conclusions based on that.

You know, if there are no Level 1 studies, you know, then you base recommendations on, say, Level 2. I guess for extremely rare interventions, it can go lower than that.

But the goal is always to sort of sort out the Level 1 evidence, lower level evidence studies will be looked at mostly to see whether or not they -- they agree or are consistent. But they're usually not used in the

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formulation of an -- of an inference.
Q. And they say, At the time of this publication, September 2013, the following met the guideline criteria.
And it lists TVT. I'll just hand it to you.
A. Yes.
Q. Do you believe that that is an accurate statement, based on your own independent scientific analysis of the data, with regard to the safety of the TVT for its intended use to treat stress urinary incontinence?
A. Yes. I mean, I agree with the statement that, you know, they only recommend the use of tapes that have had proven efficacy.
As, I'm sure, everyone is well aware, there are approximately 49 different mesh products available, some have been very well studied, others less so, some hardly at all.
And I think they were -- you know, again, they were trying to say, we

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are -- we are specifically saying that our recommendations and our clinical recommendations should be to those that have robust randomized control trial Level 1 data.
Q. And for the TVT Retropubic device, has any other device to treat stress incontinence been studied as much, as long and as broadly?
A. No. No. It is the most -- the retropubic TVT device is the most studied anti-incontinence procedure in our history.
I mean, obviously, it's the one that I do most commonly. And that is certainly based upon, you know, the quality of that data.
Q. That NICE guideline also says to use only a Type I macroporous mesh?
A. Yes, it does.
Q. Is that something you believe is a proper statement, based on the reliable scientific evidence you

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agreed -- reviewed?
A. Yes, it is.
Q. Is that an opinion you share?
A. I share that opinion.
MR. SNELL: Let's mark that.
- - -
(Whereupon, Exhibit Toglia-19, NICE Urinary Incontinence: The Management of Urinary Incontinence in Women, was marked for identification.)
- - -
BY MR. SNELL:
Q. Did you see in the plaintiffs' experts' depositions where it was observed and noted that even one of the plaintiffs' experts, when he finally decided to discuss TVT in the application to treat stress incontinence, Dr. Klinge noted, At present, the gold standard in SUI surgery is the suburethral sling, using either the tension-free vaginal tape, TVT, or the transobturator tape.

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Did you see that when you reviewed the deposition?
A. I did -- I did note that Dr. Klinge did make that statement.
Q. And he also referenced Amid Type I versus Type III in the Meshia study, where there was a 9 percent rate of erosion with the intravaginal slingplasty, compared to the zero percent with the classical TVT which he referred to as a Type I macroporous monofilament polypropylene mesh.
Do you recall that?
A. Yes.
Q. And you believe that the TVT, the retropubic TVT, is the gold standard for the treatment of stress urinary incontinence?
A. I think that the -- yes. I mean, I think that -- that synthetic midurethral slings are currently the most commonly practiced anti-incontinence procedure.
I believe that the AGS

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membership, 95 or higher, 99 percent, have done that procedure. I believe within the SUFU, or maybe it's the AUA, which is sort of our colleagues on the urology side, it's in the mid to high 80s.

The procedure is -- is the most common performed worldwide, and seems to have the highest quality of evidence.

MR. SNELL: Let's mark this as an exhibit, this being the statement by Dr. Klinge acknowledging for the application of stress urinary incontinence treatment, TVT is the gold standard in the macroporous monofilament Amid Type I mesh.

- - -

(Whereupon, Exhibit Toglia-20, Hernia Repair Surgery, Volker Schumpelick, Robert J. Fitzgibbons, Editors, was marked for identification.)

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- - -

THE WITNESS: If I might be allowed to go off the record to get a glass of water, please?

MR. SNELL: Sure.

VIDEO TECHNICIAN: We are off the record. The time is 9:20 p.m.

- - -

(Whereupon, Exhibit Toglia-21, The Cochrane Collaboration; Mid-Urethral Sling Operations for Stress Urinary Incontinence in Women (Review), was marked for identification.)

- - -

(Whereupon, a discussion off the record occurred.)

- - -

VIDEO TECHNICIAN: We are back on the video record.

BY MR. SNELL:

Q. Doctor, I've put before you Exhibit 21.

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Just if you can confirm, is that the Cochrane review that came out this year that you testified earlier about?

A. This is the 2015 Cochrane review on midurethral sling operations that was authored by Ford and colleagues.

Q. And is that a scientifically reliable Level 1 analysis?

A. The Cochrane review in front of me is thought -- is Level 1 meta-analysis, or, in other words, it's a systematic review.

Q. And in that systematic review, did they look at multiple randomized control trials?

A. Yes. They would look at Obturator versus Retropubic. They would look at whether you -- devices that were, quote/unquote, bottom to top versus top to bottom. Obturator, left to right, right to left, or, more accurately, in to out, out to in.

And I do believe there was

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some comparison that looked at types of materials as it relates to cure and time, hospital stay, complications, voiding dysfunctions.

Q. As you -- strike that.

As you do your analysis in the body of your report and you comment on the high degree of efficacy that's maintained with the TVT device in the intended treatment of stress incontinence, as well as the low complication rates and the lack of many late complications, even out to 17 years, is that of significance to you in your overall assessment as to whether the TVT is safe for the intended use of treating stress urinary incontinence?

A. Absolutely.

Q. Is that data inconsistent with plaintiffs' experts' theories of degradation, cytoxicity and other claims that there is a high rate of long-term complications?

MS. THOMPSON: Object to

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form.
THE WITNESS: It's not consistent. I'm not aware, again, of any high-quality long-term studies that suggest that there is a significant -- any significant rate -- clinical significant rate of long-term complications or harm, again, consistently on individual bases, perioperative risks, roughly in the 2 percent range for each individual thing.
Long-term, you know, what I -- what I usually sort of summarize to my patients, look, over the next ten years, the likelihood that you might have to have a re-intervention is 3 and-a-half percent.
Now, in -- if it's a prolapse patient, we say to them, look, you know, sometimes there's a 15 to 40 percent chance of reoperation for prolapse after an

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initial prolapse procedure.
These are chronic, you know, conditions, as I mentioned several times.
BY MR. SNELL:
Q. And in your report where you analyze the literature and you state, The rates of complications requiring surgery are consistently less than 5 percent across the TVT studies. Overall, the data from these high-quality long-term studies do not support the claims that TVT places a woman at a significant risk of long-term chronic complications or the need for reoperation as plaintiffs' expert suggest.
A. Yes.
Q. What did you mean by that?
A. Were you reading that from my report?
Q. Yes. That was at Page 30. I'm sorry, I should have told you where I was reading from.
A. You know, again, I was

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trying to highlight the fact that, you know, we're not -- we're not -- I wasn't asked to do an analysis for nonsurgical treatment to surgical treatment. We were looking at comparable surgical procedures.
So it's important to say, what's the baseline? All these procedures operate in the same neighborhood, and, roughly speaking, they have -- not only do they have similar rates of effectiveness, but, overall, the rates of complications are elemental. They can occur with any of them.
Bleeding with any surgery, obviously; when comparing the different techniques, the risks of bleeding are somewhat -- are somewhat similar. Although, I think the -- the Schimpf -- excuse me, the Schimpf paper suggested that, perhaps, the risk was a little lower -- excuse me, the risk was significantly lower, say, with a midurethral sling compared to a Burch.

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Bowel and bladder injuries, again, these all hovers in that sort of 2 to 3 percent range.
You know, longer -- you know -- and similar things have been seen with other procedures; the needle suspension procedures, the autologous fascial sling, what we traditionally call pubovaginal slings.
And, again, as I read through the literature and tried to come up with a number, less than 5 percent seemed, to me, to be a very conservative number that I would feel comfortable discussing with anybody with this procedure.
Q. And did you see, in some of the systematic reviews and guidelines, where the Retropubic TVT midurethral sling had better efficacy or subjective improvement than a Burch or a pubovaginal, such as Schimpf where they saw higher rates of subjective improvement so SGS actually recommends

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midurethral sling over pubovaginal sling?
A. Yes. And if I can sort of qualify that.
So in my world, we're not curing cancer, okay? We are -- we are intervening in hopes of improving one's quality of life. There are two ways you can -- you can assess that result. You know, you can simply say to the patient, you know, how do you feel? Do you feel like you have a substantial improvement? Has this resulted in a better quality of life? And that's what we would call a subjective improvement.
Stress incontinence is a complaint, it's a symptom, it's something that someone complains about. That's speaks to the subjective nature of things.
It is also a condition that can be demonstrated on testing; sometimes as simple as saying to a woman, go ahead and cough and I see if urine comes out. That's done in -- a provocative stress

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test is done in a variety of situations, sometimes with formal testing, oftentimes without formal testing.
Or you might put a pad on a woman and say, okay, you know, give me 100 jumping jacks. That's objective.
So they do tend to look at both subjective and objective. We argue back and forth with each other, what's more important. Again, being practically minded, oftentimes we'll say, you know, the patient is happy subjectively, we would give quite a bit of weight to that. So we do break them out separately. Sometimes they'll come up with a composite score.
So, fortunately, these trials were well designed and approached the -- they objectively approached both subjective measures and objective measures in both groups.
Q. And you found -- did you find those data reliable in order to be --

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A. Well, the -- I mean, yes. Many of them used the same methodologies that we use in our own randomized control trial.
MR. SNELL: No more questions. Thank you.
MS. THOMPSON: I have some follow-up questions.
- - -
EXAMINATION
- - -
BY MS. THOMPSON:
Q. First of all, in some of the articles that counsel chose to ask you about, I'm looking at the Ogah 2011 Cochrane review.
And that's one that you relied on heavily, correct?
A. Well, it's one -- yes, it's one of the studies that's -- that was part of the very large pile of Level 1 studies.
Q. And I think we're both looking at the Neurourology and

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Urodynamics summary of the Cochrane study, correct?
A. Yes. Given this is not 900 pages, I'm going to say this is the summary.
Q. Right. Could you turn to Page 289? And I'm going to read the paragraph under quality of evidence.
The quality of evidence for the majority of trials was moderate, with a minority having low to moderate levels of evidence. However, the total number of trials, 61, including 7,021 women was high and it was possible to explore the effects of different routes of insertion of the tapes and different tape materials.
On the other hand, very few trials reported outcomes after one year and the long-term efficacy and adverse events have yet to be determined.
Would you agree that, at least according to the Cochrane review of 19 -- of 2011, adverse events were yet to

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be determined?
MR. SNELL: Objection.
Misstates the document.
BY MS. THOMPSON:
Q. Did I not read that correctly, the document?
A. Um --
Q. No. First of all -- first of all, did I read that paragraph correctly?
A. You read the paragraph correctly.
And I just want -- in forming my answer, we're talking specifically about comparative trials. We're not talking about long-term trials, we're talking about, specifically, trials that randomized women to one approach, Retropubic, versus a different approach, Obturator, and the duration that the trial went on for.
This is -- this is an internal comparison between different types of midurethral slings.

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Q. But the report does say that very few trials reported outcomes after one year and the long-term efficacy and adverse events have yet to be determined, correct?
A. Very few studies that have compared one method to the other.
Q. Okay. That's what the article states, what I just read, correct?
MR. SNELL: Objection.
Asked and answered.
MS. THOMPSON: No. It's a simple question.
THE WITNESS: Again, the comparative analysis was limited to Retropubic, bottom to top versus top to bottom; Obturator, medial to lateral versus lateral to medial; monofilament versus multifilament; Transobturator versus Retropubic.
BY MS. THOMPSON:
Q. That's all true --

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A. Yes.
Q. -- but Ogah determined that the adverse events have yet to be determined.
Reading further in that -- in the section that says, Conclusions, implications for practice, the last paragraph states, However, there is little evidence about the long-term effectiveness or the chance of adverse events, such as tape erosions nor is it clear how to treat women after a tape procedure fails.
You would agree with me that that was a conclusion that Ogah made in the 2011 Cochrane review? I'm just reading it.
A. That's fine. Point to it again.
Q. The last paragraph under, Conclusions, implications for practice.
A. Right. The last sentence speaks to, you know, should you undergo a midurethral sling, that these particular

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studies analyze -- do not answer the question of what you would do subsequent.
Q. But I did read that paragraph correctly as a conclusion of Ogah in this study?
A. You did.
Q. And then in the next section, Implications for research. There is a need to address some of the limitations of a number of the trials contributed -- contributing to the synthesis, particularly in improving the methodology of the trials or their reporting. It is highly recommended that clinical trials should be reported following the CONSORT guidelines.
Did I read that paragraph correctly?
A. Yes.
Q. So Ogah, at least, states that there is -- that there are limitations to a number of these trials, and that -- particularly, improving the methodology of the trials and the

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reporting, correct?
MR. SNELL: Objection. Form.
THE WITNESS: That's their recommendations. That their -- they would like to see additional trials that would conform to the criteria that they use.
And, again, their primary objective is that they want to compare apples with apples.
BY MS. THOMPSON:
Q. And the next paragraph, in implications for research, There is a need for more robustly designed, good quality and adequately powered randomized controlled trials with standardized objectives and validated subjective outcomes. These trials need to have long-term follow-up and adequate reporting of adverse events.
Is that one of the implications for research that Ogah lists in the 2011 Cochrane review that you're

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relying on?
A. It's a suggestion.
Q. You'll agree with me that case series can be quite significant if they're reporting a new complication, correct?
MR. SNELL: Objection.
THE WITNESS: I would not agree with that, counselor, no.
BY MS. THOMPSON:
Q. So a new complication never reported about, that's published in a case series, you'll agree that those are seen frequently in prestigious journals and considered to be important?
MR. SNELL: Objection. Foundation. Compound.
THE WITNESS: I mean, I think -- I can tell you that in the journals that I work for, they are no longer interested in publishing those with any great frequency because they don't consider them to be high

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quality --
BY MS. THOMPSON:
Q. Of a new complication, never reported before?
A. Case series in general.
Q. I'm talking about case series of a new complication that has not previously been reported?
MR. SNELL: Objection.
THE WITNESS: Sure.
MR. SNELL: He's already answered this and said no.
MS. THOMPSON: He said he misunderstood my question. He thought he -- I was talking about case specific -- case series in general, and I'm talking about case series reporting a new complication.
THE WITNESS: I'm sorry.
MS. THOMPSON: Those are two different things.
THE WITNESS: I'm talking about all case series, which would

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include the type of case series that you're referring to.
BY MS. THOMPSON:
Q. Okay. And just specifically, case series reporting a new complication are deemed important frequently, correct?
MR. SNELL: Objection. Asked and answered.
THE WITNESS: Are deemed important frequently?
BY MS. THOMPSON:
Q. Are frequently deemed important in journals?
MR. SNELL: Same objection. Asked and answered.
BY MS. THOMPSON:
Q. If you disagree with it, just say you disagree with it.
A. I disagree.
I mean, just, again, I -- I serve on the editorial board and those are not manuscripts that we frequently review.

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Q. Okay. Let's look at Schimpf, another one of the articles that counsel chose to ask you about and that you relied on for your opinions, correct?
A. That is correct.
Q. Let's go to the -- to Page 71.E18.
A. I'm sorry, obviously, I'm not able to predict what you're going to ask me next, so I don't have it.
Q. I'm going to ask you about the articles that --
A. No, I'm just asking for permission to go off record so I find that article.
Q. It shouldn't take you that long.
A. No, I don't -- I'm just trying to be respectful of everybody's time on a Friday evening.
Q. Do you have Schimpf in front of you?
A. I do.
Q. Okay. If you could turn to

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Page 71.E18?
A. Counselor, I'm not sure that we're back on record.
Q. We never went off the record.
A. My apologies.
Q. And I'm reading --
A. I was waiting to hear that. So I did not focus on your question. Could you repeat that, please?
Q. 71.E18. And I'm reading from the paragraph that begins there, Limitations to the study.
And Schimpf states here, There was also high variability in reporting of numbers and types of complications in trials, making analysis of AE outcomes challenging.
And AE stands for adverse events, correct?
A. I would agree that adverse -- AE stands for adverse events.
Q. While many surgeons and patients are interested in information

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about postoperative symptoms, such as urgency and de novo urgency, these symptoms were inconsistently reported, thus limiting their analysis.
Additionally, data concerning need for re-treatment were sparse and inconsistent, limiting our ability to draw any conclusions on this important question. Complications were assessed at different time intervals among different trials, and sometimes later trials reporting secondary analysis did not update longer-term AEs. The vast majority did not use a standard classification for complications, such as the classification system of Dindo, et al.
Did I read that correctly about Schimpf's conclusions regarding the reporting of AEs?
MR. SNELL: Objection. Misstates.
Go ahead.
MS. THOMPSON: I just asked

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if I read it correctly.
BY MS. THOMPSON:
Q. Did I read it correctly, Doctor?
A. You did, counselor.
MR. SNELL: You said conclusion. So I'm going to object. That's my objection.
BY MS. THOMPSON:
Q. Are you familiar with the Brubaker paper that was published recently that was critical of two of the randomized surgical trails for urinary incontinence?
MR. SNELL: Form. Vague.
THE WITNESS: Dr. Brubaker is so prolific, I don't know which one you're talking about.
BY MS. THOMPSON:
Q. The title is, Missing Data Frequency and Correlates in Two Randomized Surgical Trials for Urinary Incontinence in Women.
A. I'm not familiar with that,

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no.
Q. So you -- and it's in the IUJ, do you read that journal that you're the editor of?
A. I read that journal. I can't tell you I read everything that's published within that journal.
Q. Would that have been something interesting to you, to determine that two randomized surgical trials had missing visits and data increasing with time?
MR. SNELL: Objection. Calls for speculation.
THE WITNESS: All -- all clinical trials suffer from that occurrence.
BY MS. THOMPSON:
Q. At least somebody at the IUJ thought that was significant enough to be published, correct?
MR. SNELL: You're asking him to comment on something that he doesn't recall seeing? If

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you've got it --
BY MS. THOMPSON:
Q. You can answer.
MR. SNELL: If you've got it, print it out and put it on the record. I don't care. But don't ask him to speculate.
BY MS. THOMPSON:
Q. You can -- you can answer the question.
A. It was published, so an editor felt that it was worthy of publication.
Q. Are you aware of publications reporting inflammatory tumors associated with the TVT?
MR. SNELL: Objection. Form. Foundation. Associated.
THE WITNESS: I'm sorry, I'm not familiar -- I'm not aware of a publication that makes -- makes that claim, no.
BY MS. THOMPSON:
Q. Have you ever researched to

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see if there are benign inflammatory tumors associated with TVT?
MR. SNELL: Objection. Relevance.
THE WITNESS: In the research that I did in formulating my opinion, I did not come across such an article.
BY MS. THOMPSON:
Q. What is your definition of a medical device?
A. A medical device, I would consider to be -- I think in the United States devices need to be approved by the FDA and the -- excuse me, the specific indication for that device needs to be stated.
Q. You've used the word "approved" several times today.
Do you mean cleared?
A. I suspect that I mean cleared. To me, approved, cleared.
Q. And so you're not claiming to be a regulatory expert, correct?

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A. I'm familiar with the regulatory process, probably more so than the average citizen.
Q. And, yet, you don't know the difference between cleared and approved?
A. I'm saying that I use both terms interchangeably.
Q. So those two terms are interchangeable in your mind?
A. I mean, approved, to me, means it's approved for use.
Q. Is the answer yes?
A. I consider them in the same -- in the same light.
Q. I'm going to read you the World Health Organization definition of medical device and ask you if you would agree with that definition, okay?
A. Okay.
Q. Medical device means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article intended by

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the manufacturer to be used alone or in combination for human beings for one or more of the specific medical purposes of...

Does that sound like a definition of medical device -- device that you would agree with?

MR. SNELL: Objection. Foundation.

THE WITNESS: I'll take what you say at face value, counselor. That sounds like a reasonable definition.

BY MS. THOMPSON:

Q. Were PROLENE® sutures cleared by the FDA?

A. I don't believe that PROLENE® sutures, per se, are considered a medical device.

Q. That wasn't my question.

My question was, were PROLENE® sutures cleared by the FDA as a medical device?

A. I thought that's what I just

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said. I mean, I don't know. I'm not aware that they are, A, categorized by a medical device. If they were categorized by a medical device, I would assume they were cleared. But I don't know what category sutures fall into.

Q. I'll represent to you that sutures -- PROLENE® suture was cleared by the FDA as a --

MR. SNELL: That is a total misrepresentation.

BY MS. THOMPSON:

Q. -- approved by the FDA as a medical device.

MR. SNELL: It was approved as a drug by the FDA, found to be safe and effective. You know that's a blunt misrepresentation to the witness. And then re-categorized as a device.

MS. THOMPSON: Forgive me. It was re-categorized as a device.

BY MS. THOMPSON:

Q. Would a suture fit the

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medical device that I -- definition that I just read to you from the World Health Organization?

MR. SNELL: Form.

THE WITNESS: I don't -- I'd have to see it again, sort of -- in writing, counselor. That a rather complicated --

BY MS. THOMPSON:

Q. Is it a material?

A. A suture is a material.

Q. Does a suture usually come with a needle attached?

A. It may or may not have a needle attached.

Q. If it does have a needle attached, is that an apparatus?

A. I would assume that it could be considered an apparatus.

Q. Is it used for human beings?

A. Yes.

Q. Is it used for a medical purpose?

A. Yes.

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Q. Wouldn't you agree that that fits the definition of the World Health Organization of a medical device?

MR. SNELL: Objection to form.

THE WITNESS: The way that you described it to me, I would take your word that that's how it is classified.

BY MS. THOMPSON:

Q. Okay. Thank you.

Did I hear you correctly that you track your complications in your practice using mental notes?

MR. SNELL: Misstates. Go ahead.

THE WITNESS: We track our complications on -- on spreadsheets, on paper.

BY MS. THOMPSON:

Q. And we could request those spreadsheets and papers that track your complications?

A. I don't know that those

exist beyond a certain period of time. They're not published.

Q. And you don't have those in your office that we can look at?

A. I'm sorry, I do not.

MS. THOMPSON: I have --

BY MS. THOMPSON:

Q. Oh, I have another question.

If I were to show you internal Ethicon documents that show degradation, show surface cracking, show the clinical significance and show the histological diagnosis of degradation, would you still hold on to your opinion that polypropylene does not degrade?

MR. SNELL: Objection. Foundation. Form.

THE WITNESS: I would. Because, again, the Level 1 evidence on safety would trump lower levels of evidence, which would include in vitro studies that you're referring to or even animal studies.

MS. THOMPSON: No further questions.

MR. SNELL: No questions.

VIDEO TECHNICIAN: This concludes the deposition. We are off the record. The time is 9:50 p.m.

- - -

(Whereupon, the deposition concluded at 9:50 p.m.)

- - -

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

Amanda Maslynsky-Miller
Certified Realtime Reporter
Dated: October 5, 2015

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I,_____, do hereby certify that I have read the foregoing pages, 1 - 415, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
MARC TOGLIA, M.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

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Notary Public

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